



Literature review: A review of couple based interventions for PTSD and relational functioning in military populations and their partners

Empirical study: The association between maladaptive emotion regulation and cause of injury type in UK military veterans with co-occurring TBI and PTSD

Submitted by Mark Rose, to the University of Exeter
as a thesis for the degree of Doctor of Clinical Psychology, May 2016

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Signature: 

Author's Declaration

The literature review was completed independently by the author. In terms of the empirical work, 123 participants were recruited as part of a study titled "Prevalence and associations between traumatic brain injury and mental health difficulties with UK veterans accessing support for mental health difficulties" (Murphy, Palmer, Wessely, Oddy, Ramos, Fortescue & Busuttil, 2015) between January 2014 to December 2014. The author conducted secondary data analyses on the original dataset and follow-up data collection on a total of 33 participants from the original sample between September 2015 to January 2016. All other aspects of the study were completed by the author including data entry, analysis and write up.

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SCHOOL OF PSYCHOLOGY
DOCTORATE IN CLINICAL PSYCHOLOGY

LITERATURE REVIEW

**A review of couple based interventions for PTSD and relational
functioning in military populations and their partners**

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Abstract

Background: Military-related stressors can adversely affect veterans' mental health, in particular PTSD. This can have a detrimental impact on intimate relationships and family adjustment. To date, couple based interventions for PTSD and relational functioning in military couples have not been systematically reviewed.

Objectives: This review summarises and synthesises literature investigating couple based interventions for PTSD and relational functioning in military couples.

Method: A systematic review of all literature to date across 24 databases using an advanced combination of search terms. Ten studies were included (nine USA; one Australian).

Results: A wide range of couple based interventions were identified: complementary and alternative therapies (CAM), sport and recreation programmes, retreats, courses as well as structured disorder focused couple therapies. There was preliminary evidence of support for couple based interventions treating PTSD, with relatively stronger support for disorder focused couple therapies over sports and recreation activities, CAM and retreats/courses. There was relatively little support for improved relational functioning assessed in couple based interventions treating PTSD. However, spouses tended to report a greater degree of improved relational functioning compared to veterans.

Conclusions: There was relatively stronger evidence to support disorder focused couple therapies over other treatment modalities. However, there was a lack of robust designs used in effectiveness research of couple based interventions in military populations. There is potential for couple based interventions to be effective in treating PTSD in the UK military.

Keywords: Military veterans, couples interventions, mental health, relationships.

Introduction

Military deployment presents substantial challenges to military populations¹ and their family system (Gimbel & Booth, 1994; Kulka et al., 1988). Two broad categories of military-related stress exist, a) deployment stressors e.g., separation difficulties, and b) war zone exposure, e.g., combat involvement. During the early phases of deployment, changes in roles and routines may take an emotional toll on military spouses, e.g., increased loneliness, anxiety and depression (Mansfield et al., 2010; Steel-Fisher, Zaslavsky, & Blendon, 2008). Post-deployment, positive and negative emotions may challenge the family, e.g., relief the loved one has returned home but managing discrepant expectations around renewing emotional and sexual intimacy (Marek et al., 2012; U.S. Army, 2007).

War zone exposure such as combat engagement are associated with higher rates of physical and psychological concerns, e.g., amputations or post-traumatic stress disorder (PTSD) (Fisher, 2007) compared to rates found in civilian populations. Physical injuries increase the risk of subsequent psychological disorders, e.g., depression or PTSD (Koren, Norman, Cohen, Berman, & Klein, 2005; MacGregor, Corson, Larson, & Shaffer, 2009). Of combat-injured veterans who screened negative for depression or PTSD one-month post injury, 80% subsequently screened positive for either at seven-month follow-up (Grieger et al., 2006).

Relational functioning refers to the degree to which a family or couple meet the emotional and functional needs of its members (Venes, 2005). The robust negative association between psychological disorders and relational functioning in civilians (e.g. Whisman, Uebelacker, & Bruce, 2006) exists to an even greater degree in military populations (e.g. Mansfield et al., 2010). Relational dysfunction has been associated with veteran physical injuries (Collins & Kennedy, 2008) and psychological disorders, in particular PTSD and depression (Sayer, Farrow, Ross, & Oslin, 2009). Divorce rates have been independently positively associated with veteran combat exposure, depression and PTSD (Cotton, 2009;

¹ The following terms are often used to describe military populations: 'veteran', 'combat veteran', 'war veteran', 'injured service member', 'military personnel', and 'ex-military personnel'. However, none of them are clearly defined (Burdett et al., 2012). For the purpose of this review, the term 'veteran' will be used to describe former serving members of the armed forces, 'military personnel' will be used to describe active duty personnel, whereas 'military populations' encompasses both, unless otherwise stated.

Ruger, Wilson, & Waddoups, 2002). Regarding partner mental health, a review revealed evidence of carer burden and distress (Yambo & Johnson, 2014) as well as secondary traumatization (Dekal & Solomon, 2007). Williamson (2012) reported high levels of concern about the impact of family reintegration, particularly around issues of control, e.g. decision making, leading to potential conflict and abuse. Intimate partner violence (IPV) is up to three times higher in military versus civilian couples (Jones, 2012).

Galovski and Lyons (2004) reported veterans with PTSD were more likely to report lower relational functioning, be divorced or were considering divorce, or perpetrate IPV. PTSD severity can mediate the relationship between pre-existing negative emotionality and post-deployment relationship functioning (Meis, Erbes, Polusny, & Compton, 2010), e.g., avoidance of emotional involvement and expression may reduce opportunities for intimacy and effective communication, whilst hyperarousal via irritability and anger can lead to ineffective problem solving and decreased social support (Sherman, Zanotti, & Jones, 2005).

Trauma focused cognitive behavioural therapy (CBT) and eye movement desensitization and reprocessing (EMDR) are the most efficacious approaches for PTSD (e.g. Cusack et al., 2016). Two systematic reviews of individual and group based psychosocial therapies for PTSD in military populations showed evidence for the efficacy of trauma focused therapies (Kitchiner, Roberts, Wilcox, and Bisson (2012) and cognitive processing and prolonged exposure therapies (Steenkamp, Litz, Hoge, and Marmar (2015). Yet individual based therapies may not cater for the co-occurring challenges before, during and after deployment that face military families. A systemic approach may be helpful in light of a) the way in which military life and deployment affects family members; b) family engagement is associated with improved outcomes in a variety of psychological disorders (Falloon, Roncone, Held, Coverdale, & Laidlaw, 2002); c) family members can be an important conduit to treatment by helping veterans overcome mental health stigma (Milliken, Auchterlonie, & Hoge, 2007); d) veterans report a preference for greater family involvement in mental health treatment (Batten et al., 2009; Khaylis, Polusny, Erbes, Gewirtz, & Rath, 2011), especially partners (Hershenberg, Mavandadi, Klaus, Oslin, & Sayers, 2014).

Aim

Scarce previous research has highlighted military-related stressors can adversely affect veterans' mental and physical health, in particular PTSD, and the detrimental impact this has on intimate relationships and family adjustment (Dekel & Monson, 2010; Monson, Taft, & Fredman, 2009). Makin-Byrd, Gifford, McCutcheon, and Glynn (2011) highlight the benefits of currently available systemic based interventions in the Veterans Health Administration (VHA), e.g., psychoeducation programmes such as support and family education (Sherman, 2006) and behavioural family therapy (Mueser & Glynn, 1999). However, couple based interventions for PTSD in military couples have not been systematically reviewed to date. Couple interventions were not included in reviews by Kitchiner et al. (2012) and Steenkamp et al. (2015) as they focused on individual or group based interventions. Synthesis of the current evidence base for couple based interventions for PTSD in military couples may help with intervention and policy recommendations. This review aims to systematically examine the literature on the effectiveness of couple based interventions for PTSD in military couples.

Research Question

Are couple based interventions for PTSD effective in military populations and their partners?

Methods

Search Strategy and Information Sources

A systematic search of published peer reviewed articles up to 2015 was conducted in December 2015 across 24 databases (Figure 1).

Search terms.

The following terms were used to search titles, abstracts and key words using population, interventions and outcomes (PICO; O'Connor, Green, & Higgins, 2011):

Population: soldier OR army OR air force OR navy OR royal marine OR military OR military personnel OR armed forces OR ex-military OR veteran OR combat AND famil* OR husband OR wife OR wives OR spouse OR partner OR military famil*

Interventions: psychological intervention OR rehabilitation OR CBT OR family OR systemic OR therapy OR counselling OR couples OR interpersonal OR treatment

Outcomes: mental health OR psychological health OR emotional health OR family functioning OR family dysfunction OR well-being OR psychosocial

Eligibility Criteria

Inclusion criteria were:

Population: Adult men or women who are military personnel (i.e. currently serving) or veterans (ex-service); partner/spouse of military personnel or veterans.

Interventions: Any couple-based psychological treatment for PTSD.

Comparisons: Any comparison such as waiting list, treatment as usual, and other interventions.

Outcomes: Any outcome related to PTSD.

Study designs: Longitudinal observation studies, non-controlled trials, controlled trials (both randomised and non-randomised).

Exclusion criteria were: Psychological treatment studies for mental health disorders and family dysfunction in non-military families; studies investigating mental health symptoms and disorders other than PTSD as primary outcomes in military families; studies investigating IPV as primary outcomes in military families; studies investigating physical health as primary outcomes in military

families; studies investigating non-couple-based systemic interventions²; couple-based interventions that included non-partner/spouse participants; *preventative* systemic interventions³; articles that were not in English; the following study designs: cross-sectional surveys, case study/case series, qualitative studies, cohort studies (historical and classical), ecological studies and reviews.

Data Extraction and Quality Appraisal

Data extraction expanded the PICO system (O'Connor et al., 2011), summarised in Table 1. Included studies were quality appraised using STROBE: Qualitative Appraisal Tool for Studies in Epidemiology (Vandenbroucke et al., 2007, Appendix A). The STROBE Statement consists of a checklist of 22 items to ensure the quality of reporting of observational studies. The quality score was the number of items from the STROBE checklist addressed as a percentage of the total number of items applicable.

² Bronfenbrenner (1979) ecological definition of *systemic* also includes systems beyond the service user, i.e., immediate family, extended family, occupation, community and culture. Systemic interventions in this review focused exclusively on the “couple” level, thus interventions such as multi-generation family, child parenting, service-level (e.g. staff training), occupational level (e.g. promoting resilience), or community level (e.g. educational or vocational skills) were excluded.

³ *Preventative* systemic interventions are those aimed at preventing distress or enhancing relationships or well-being as opposed to *rehabilitative*, i.e., treatment for symptoms, distress or dysfunction.

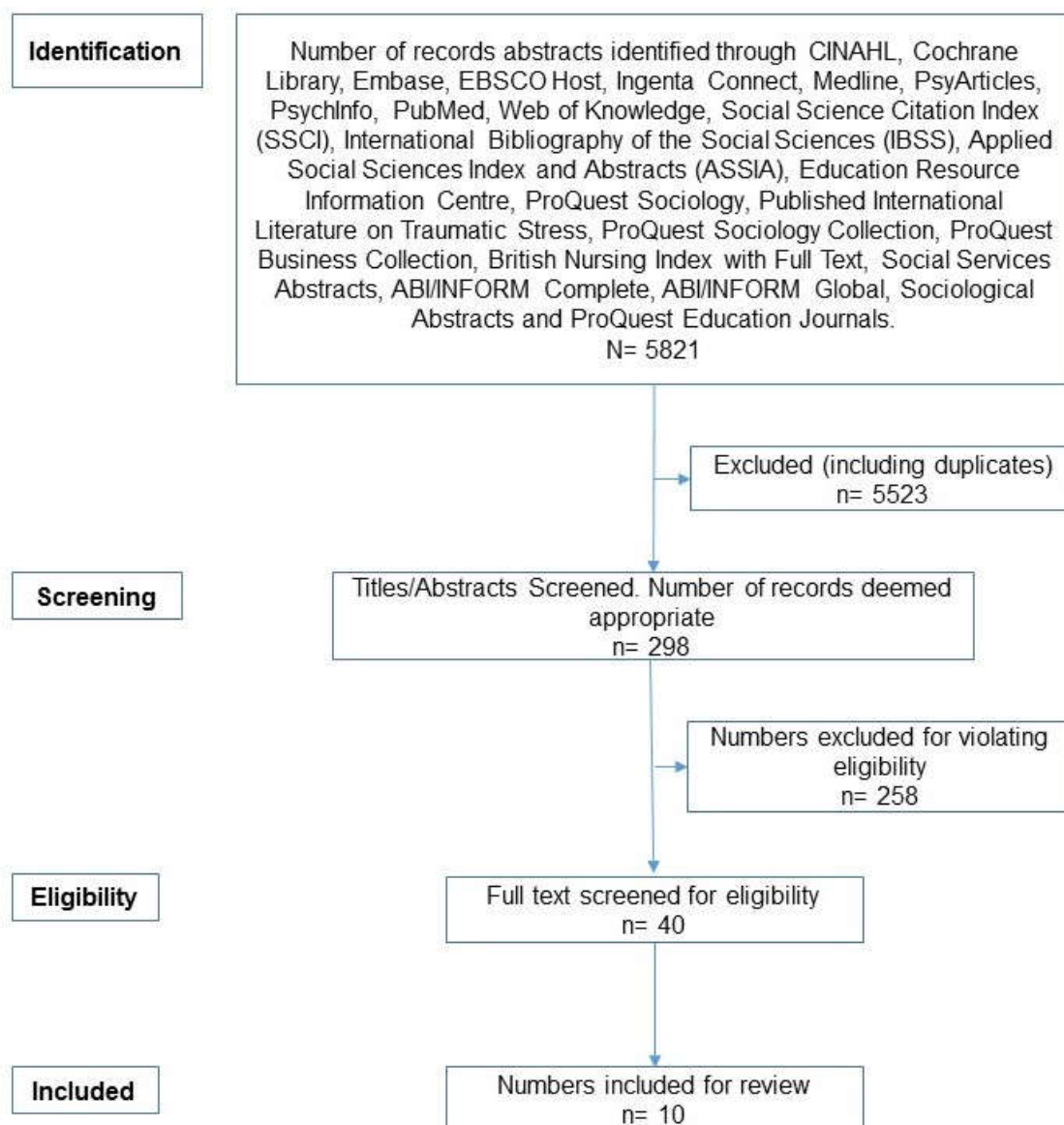


Figure 1. Search strategy, process of identification, screening, eligibility and inclusion for review.

Results

A total of 5821 abstracts were identified. Screening of titles and abstracts revealed 298 full papers. Application of inclusion and exclusion criteria resulting in ten included papers for review (Figure 1).

Design

One study was a randomised controlled trial (RCT; study 8), two studies used a non-randomised controlled design (study 1 and 4), the remaining were within-group uncontrolled trials comparing pre vs. post intervention outcomes.

Table 1. Summary of included studies

Study number, author & year	Study aims and treatment type	Design, method and recruitment	N (n per condition/ phase)	Study and demographic information	Main outcome measures	Key findings and effect sizes	STROBE percentage of criteria met & quality appraisal
1) Bennett, Lundberg, Zabriskie, and Eggett (2014)	1o: Evaluate effectiveness of sport and recreation "Higher Ground" couples program in reducing PTSD symptoms, facilitating posttraumatic growth and enhancing marital satisfaction	Design: Non-randomised controlled trial Conditions: Repeated measures: baseline; post-treatment Groups- Group A: Program Group B: Program + communication skills Group C: Control	N= 17 dyads Group A: 5 dyads Group B: 6 dyads Controls: 6 dyads	Country: USA Service: Mixed; OIF/OEF exposure Status: Not explicitly stated (NES) Length relationship: NES Age veteran: \bar{x} 37; 35; 41 years Age spouse: \bar{x} 33; 32; 41 years Education: NES	All measures completed by veteran and spouse PTSD measure: PTSD Checklist- Military or Civilian Relational functioning measures: Revised Dyadic Adjustment Scale	PTSD: Significant reduction in PTSD symptoms for Group A ($p= 0.002$) and B ($p= 0.032$). Relationship: Significant improvement in marital satisfaction for Group B ($p= 0.009$). No effect sizes reported. Authors concluded couples sports and recreation program can be used to help reduce PTSD symptoms and increase marital adjustment and satisfaction.	Percentage criteria met: 77% Strengths: Limitations: Small sample size Non-randomised design

Study number, author & year	Study aims and treatment type	Design, method and recruitment	N (n per condition/ phase)	Study and demographic information	Main outcome measures	Key findings and effect sizes	STROBE percentage criteria met & quality appraisal
2) Collinge, Kahn, and Soltysik (2012)	<p>1o: Phase 1 feasibility study for use of self-directed complimentary and alternative therapies “Mission Reconnect” for National Guard veterans and their partners</p> <p>Treatment type: Complimentary and alternative medicine</p>	<p>Design: Uncontrolled trial</p> <p>Conditions: Within-group only Repeated measures: baseline; 4 week FU; 8 week FU</p>	<p>Baseline data collected: N= 41 dyads</p> <p>Began intervention: n= 38 dyads</p> <p>Completed follow-up: n= 32 dyads</p>	<p>Country: USA</p> <p>Service: Army National Guard</p> <p>Status: AD</p> <p>Length relationship: NES</p> <p>Age veteran: \bar{x} 34 years (sd= 6.7)</p> <p>Age spouse: \bar{x} 29.3 years (sd= 6.9)</p> <p>Education: Up to MA</p>	<p>All measures completed by veteran and spouse</p> <p>PTSD measure: PTSD Checklist-Civilian (spouse rated own symptoms)</p> <p>Relational functioning measures: Compassionate Love Scale</p>	<p>PTSD: For veterans, significant reduction in symptoms at 4 week FU ($p < 0.003$) and 8 week FU ($p < 0.003$). For spouses, significant reduction at 4 week FU ($p < 0.026$) and 8 week FU ($p < 0.009$).</p> <p>Relationship: For veterans, NS improvement on Compassionate Love Scale at 4 week FU ($p < 0.212$) and 8 week FU ($p < 0.453$). For spouses, NS improvements at 4 week FU ($p < 0.513$) and 8 week FU ($p < 0.216$).</p> <p>No effect sizes reported.</p> <p>Authors concluded intervention can significantly reduce PTSD and increase self-compassion for both veterans and their partners during the reintegration process.</p>	<p>Percentage criteria met: 89%</p> <p>Strengths: Pilot data that will be used to inform an RCT</p> <p>Limitations: No control group</p> <p>Discrepant reporting of data analysis-loss to follow-up = 12, yet repeated measures analyses states 41 were analysed</p> <p>No multiple testing correction applied thus</p>

Study number, author & year	Study aims and treatment type	Design, method and recruitment	N (n per condition/ phase)	Study and demographic information	Main outcome measures	Key findings and effect sizes	STROBE percentage criteria met & quality appraisal
				Ethnicity: Caucasian (n= 74); Hispanic (n= 5); African American (n= 3); Native American (n= 4)			may be prone to Type 1 errors, e.g. if using adjusted <i>p</i> value of 0.0025 for outcome measures, findings for PTSD and self-compassion become NS. However no difference to main findings when adjusted <i>p</i> value= 0.004 applied

Study number, author & year	Study aims and treatment type	Design, method and recruitment	N (n per condition /phase)	Study and demographic information	Main outcome measures	Key findings and effect sizes	STROBE percentage criteria met & quality appraisal
3) Devilly (2002)	<p>1o: Assess effectiveness of 5-day Lifestyle Management course for veterans and their partners</p> <p>Treatment type: Course</p>	<p>Design: Uncontrolled trial</p> <p>Conditions: Within-group only Repeated measures: baseline; post-treatment; 3 month FU; 6 month FU</p>	<p>Baseline: n=209 (111 veterans; 98 spouses)</p> <p>Post-treatment: n=207 (110 veterans; 97 spouses)</p> <p>3 month FU: n= 165 (86 veterans; 79 spouses)</p> <p>6 month FU: n= 141 (74 veterans; 67 spouses)</p>	<p>Country: Australia</p> <p>Service: NES; Vietnam veterans</p> <p>Status: NES</p> <p>Length relationship: NES</p> <p>Age veterans: \bar{x} 58.19 years (sd= 4.13)</p> <p>Age spouses: \bar{x} 48.38 years (sd= 4.81)</p> <p>Education: NES</p>	<p>Measures completed by veteran and spouse except IES</p> <p>PTSD measure: Impact of Events Scale (veterans only)</p> <p>Relational functioning measures: Abbreviated Dyadic Adjustment Scale</p>	<p>PTSD: Baseline to post treatment showed significant decrease in symptoms ($p= 0.0001$, $d= 0.42$). Repeated measures over 4 time points showed NS improvement in symptoms for veterans ($p= 0.07$; $\eta_p^2= 0.04$). At 6 month FU, 22.54% had reliably improved; 9.86% had reliably worsened.</p> <p>Relationship: Repeated measures over 4 time points showed NS improvement in relationship satisfaction ($p= 0.07$; $\eta_p^2= 0.02$).</p> <p>Authors concluded drop in PTSD symptomatology for the veterans was of minimal clinical utility given small effect size at FU.</p>	<p>Percentage criteria met: 95%</p> <p>Strengths:</p> <p>Limitations: Lacks control group</p>

Study number, author & year	Study aims and treatment type	Design, method and recruitment	N (n per condition/ phase)	Study and demographic information	Main outcome measures	Key findings and effect sizes	STROBE percentage criteria met & quality appraisal
4) Ford et al. (1993)	<p>1o: Assess effectiveness of psychosocial debriefing program in reducing stress related symptoms and improving family satisfaction</p> <p>Treatment type: Course</p>	<p>Design: Non-randomised controlled trial</p> <p>Conditions: Repeated measures: Baseline; Post-treatment</p> <p>Groups: Treatment vs. control groups</p>	<p>Phase III findings only:</p> <p>Treatment group at baseline N= 82 (veterans n= 58; spouse n= 24)</p> <p>Treatment group at post-treatment: N= 79 (veterans n= 57; spouses n= 22).</p> <p>Control group at baseline: N= 31 (veterans n= 24; spouses n= 7).</p>	<p>Country: USA</p> <p>Service: Reserve and National Guard</p> <p>Status: AD</p> <p>Length relationship: NES</p> <p>Age: NES</p> <p>Education: NES</p> <p>Ethnicity: NES</p>	<p>All measures completed by veteran and spouse</p> <p>PTSD measure: Impact of Events Scale (4 ratings collected: Intrusion score for deployment stressor; Intrusion score for post-deployment stressor; Avoidance score for deployment stressor; Avoidance score for post-</p>	<p>Using MANOVA, veterans reported significantly improved post-treatment scores on combined dependent variables: significant main effect of treatment ($p= 0.03$); significant main effect of time ($p= 0.003$); significant treatment* time interaction ($p= 0.035$). Univariate analyses of-</p> <p>PTSD: Significant main effect of treatment for 3 PTSD ratings (NS for Intrusive post-deployment). Significant main effects of time for all 4 PTSD ratings. Significant treatment*time interaction effect for Avoidance post-deployment, in that treatment group showed larger positive change than control group ($p= 0.03$).</p>	<p>Percentage criteria met: 59%</p> <p>Strengths:</p> <p>Limitations: Self-selecting groups (either treatment seeking or non-treatment seeking), not randomised</p> <p>No multiple testing correction applied to univariate analyses thus may be prone to Type 1 errors. If using adjusted p</p>

Study number, author & year	Study aims and treatment type	Design, method and recruitment	N (n per condition/ phase)	Study and demographic information	Main outcome measures	Key findings and effect sizes	STROBE percentage criteria met & quality appraisal
			Control group at post: treatment- N= 25 (veterans n= 19; spouses n= 6)		deployment stressor) Relational functioning measures: Locke Wallace Marital Adjustment Scale (Global Satisfaction Rating reported) Family APGAR	Relationship: The MGSR revealed NS main effect of treatment ($p= 0.34$), NS main effect of time ($p= 0.30$). Significant treatment*time interaction, in that treatment group increased satisfaction at post-treatment whilst control group decreased at post-treatment ($p= 0.001$). Family APGAR showed NS main effects of treatment, time and interaction. Effect sizes not reported. Authors concluded participation in a couple-based intervention during the acute phase of reunion appeared to assist veterans in beginning re-adjustment process, and spouses in integrating separation stressor experiences.	value of 0.007, main effect of treatment for PTSD Intrusive deployment stressor and treatment*time interaction PTSD Avoidance post-deployment become NS.

Study number, author & year	Study aims and treatment type	Design, method and recruitment	N (n per condition/ phase)	Study and demographic information	Main outcome measures	Key findings and effect sizes	STROBE percentage criteria met & quality appraisal
5) Monson, Schnurr, Stevens, and Guthrie (2004)	<p>1o: Determine efficacy of Cognitive Behavioural Couples Treatment (CBCT) for PTSD</p> <p>Treatment type: Disorder focused systemic couple therapy</p>	<p>Design: Uncontrolled trial</p> <p>Conditions: Within-group only Repeated measures: baseline; post-treatment</p>	N= 7 dyads	<p>Country: USA</p> <p>Service: NES; Vietnam exposure</p> <p>Status: NES</p> <p>Length relationship: \bar{x} 29 years (range= 2 - 35)</p> <p>Age veteran: \bar{x} 56 years (range= 53 - 58)</p> <p>Age spouse: \bar{x} 51 (range= 42 - 59)</p> <p>Education: NES</p> <p>Ethnicity: Caucasian (n= 14)</p>	<p>PTSD measure: Clinician Administered PTSD Scale (veteran)</p> <p>PTSD Checklist (veteran and spouse's rating of veteran PTSD)</p> <p>Relational functioning measures: Dyadic Adjustment Scale (veteran and spouse)</p>	<p>PTSD: CAPS showed significant improvement ($p < 0.01$, $d = 1.60$); 7 veterans showed reliable improvement.</p> <p>PCL- self report showed NS improvement ($d = 0.64$); 4 veterans showed reliable improvement whilst 1 veteran shown reliable worsening.</p> <p>PCL- partner report showed significant improvement ($p < 0.05$, $d = 1.18$); 5 veterans showed reliable improvement.</p> <p>Relationship: Veterans showed NS deterioration ($d = 0.05$); 2 showed reliable deterioration. Partner showed marginally NS improvement ($p = 0.07$, $d = -0.92$), 3 showed reliable improvement.</p> <p>Authors concluded evidence of preliminary support for use of CBCT in veterans with chronic and severe PTSD.</p>	<p>Percentage criteria met: 84%</p> <p>Strengths: Reliability change calculated for each outcome</p> <p>Limitations: Small sample, uncontrolled study and lacks follow-up</p>

Study number, author & year	Study aims and treatment type	Design, method and recruitment	N (n per condition/ phase)	Study and demographic information	Main outcome measures	Key findings and effect sizes	STROBE percentage criteria met & quality appraisal
6) Sautter, Glynn, Arseneau, Cretu, and Yufik (2014)	<p>1o: Pilot study of effectiveness of Strategic Approach Therapy in reducing PTSD symptoms and relational distress in OIF veterans and spouses</p> <p>Treatment type: Disorder focused systemic couples therapy</p>	<p>Design: Uncontrolled trial</p> <p>Conditions: Within-group only Repeated measures: baseline; post-treatment</p>	N= 7 dyads	<p>Country: USA</p> <p>Service: NES; OIF exposure</p> <p>Status: NES</p> <p>Length relationship: \bar{x} 7.1 years (sd= 6.8)</p> <p>Age veteran: \bar{x} 38.7 years (sd= 10.8)</p> <p>Age spouse: \bar{x} 35.4 (sd= 9.8)</p> <p>Education: NES</p>	<p>PTSD measures: Clinician Administered PTSD Scale (veteran)</p> <p>PTSD Checklist (veteran)</p> <p>Relational functioning measures: Dyadic Adjustment Scale (veteran and spouse)</p>	<p>PTSD: CAPS: significant improvement ($p=0.001$, $g=3.54$).</p> <p>PCL-M: significant improvement ($p=0.001$, $g=2.51$).</p> <p>All veterans showed a positive reliable change on CAPS and PCL-M.</p> <p>Relationship: NS improvement for both veteran ($g=0.52$) and spouse ($g=0.63$). 5/7 veterans and 4/7 spouses showed positive reliable change; 1/7 veterans and 1/7 spouses showed reliable worsening.</p> <p>Authors concluded SAT associated with significant reductions in PTSD symptoms. Some evidence can improve relationship functioning but not as great a benefit.</p>	<p>Percentage criteria met: 89%</p> <p>Strengths:</p> <p>Limitations: Non-controlled design</p> <p>No follow-up assessment</p>

Study number, author & year	Study aims and treatment type	Design, method and recruitment	N (n per condition/ phase)	Study and demographic information	Main outcome measures	Key findings and effect sizes	STROBE percentage criteria met & quality appraisal
7) Sautter, Glynn, Thompson, Franklin, and Han (2009)	1o: Preliminary study to determine effectiveness of Strategic Approach Therapy (SAT) in reducing PTSD symptoms Treatment type: Disorder focused systemic couples therapy	Design: Uncontrolled trial Conditions: Within-group only Repeated measures: Baseline; post-treatment	N= 6 dyads	Ethnicity: Caucasian (n= 12); African American (n= 2)	PTSD measures: Clinician Administered PTSD Scale	Overall PTSD severity: Significant reduction as reported by PCL self-report ($p < 0.001$), PCL-partner ($p < 0.015$) and CAPS ($p < 0.002$).	Percentage criteria met: 73%
				Country: USA Service: NES; Vietnam exposure Status: D Length relationship: 2 dyads: 20-30 years 4 dyads: 30-40 years Age veteran: \bar{x} 59.2 years Age spouse: \bar{x} 53.1 years	PTSD Checklist (both veteran and spouse's rating of veteran PTSD) Relational functioning measures: None	Effortful avoidance: Significant reduction as reported by PCL self-report ($p < 0.003$), CAPS ($p < 0.007$). NS reduction by PCL-partner ($p > 0.05$). Emotional numbing: Significant reduction as reported by PCL self-report ($p < 0.003$), PCL-partner ($p < 0.007$) and CAPS ($p < 0.0002$). Hyperarousal: NS reduction as reported by PCL self-report, PCL-partner and CAPS (all $p > 0.05$).	Strengths: Limitations: Small sample and uncontrolled design. No measure of relational functioning

Study number, author & year	Study aims and treatment type	Design, method and recruitment	N (n per condition/ phase)	Study and demographic information	Main outcome measures	Key findings and effect sizes	STROBE percentage criteria met & quality appraisal
				Education: NES Ethnicity: Caucasian (n= 8); African American (n= 4)		Re-experiencing: Significant reduction as reported by PCL self-report ($p < 0.001$). NS reduction by PCL- partner and CAPS (both $p > 0.05$). No effect sizes reported. Authors concluded preliminary evidence that SAT can reduce avoidance, emotional numbing and overall PTSD severity.	
8) Sautter, Glynn, Cretu, Senturk, and Vaught (2015)	1o: Assess efficacy of Strategic Approach Therapy against an active comparator-PTSD family education Treatment type: Disorder focused systemic	Design: Randomised controlled trial Conditions: Repeated measures: Baseline; post-treatment; 12 week FU Groups: Treatment-Strategic Approach Therapy (SAT)	N= 57 dyads Baseline: SAT: 29 dyads PFE: 28 dyads Post-treatment: SAT: 22 dyads PFE: 21 dyads 12 week FU: SAT: 21 dyads (76% retention at FU) PFE: 20 dyads (75% retention at FU)	Country: USA Service: NES; OEF/OIF exposure Status: NES Length relationship: NES Age veteran:	PTSD measures: Clinician Administered PTSD Scale (veteran) PTSD Checklist-Military (veteran) Relational functioning measures: Dyadic Adjustment	PTSD: Veterans in both SAT and PFE groups showed significant reductions in CAPS and PCL-M at post-treatment (CAPS: SAT $p < 0.0001$, PFE $p < 0.01$; PCL-M: SAT $p < 0.0001$, PFE $p < 0.02$). Effects maintained at FU (CAPS: SAT $p < 0.0001$, PFE $p < .01$; PCL-M: SAT $p < 0.0001$, PFE $p < 0.004$). Significant treatment*time interaction effect- SAT group exhibited greater rate of	Percentage criteria met: 95% Strengths: General Linear Mixed Modelling used to account for demographics , differing mean number of sessions between SAT and PFE and severity of

Study number, author & year	Study aims and treatment type	Design, method and recruitment	N (n per condition/ phase)	Study and demographic information	Main outcome measures	Key findings and effect sizes	STROBE percentage criteria met & quality appraisal
	couples therapy	Control- PTSD family education (PFE)		<p>SAT: \bar{x} 32.55 years (sd= 6.16)</p> <p>PFE: \bar{x} 33.71 years (sd= 7.01)</p> <p>Age spouse: SAT: \bar{x} 32.17 years (sd= 7.68) PFE: \bar{x} 32.25 (sd= 7.89)</p> <p>Education veteran: Up to MA</p> <p>Education spouse: Up to PhD/MD</p>	<p>Scale (veteran and spouse)</p> <p>Experiences in Close Relationship-Revised (veteran and spouse)</p>	<p>improvement compared to PFE group at post-treatment (CAPS: $p < 0.0001$; PCL-M $p < 0.0007$) and FU (CAPS: $p < 0.0001$; PCL-M: $p < 0.0006$).</p> <p>PTSD remission: 15 veterans participating in SAT (52%) and 2 veterans in PFE (7%) no longer met PTSD diagnostic criteria at FU.</p> <p>(CAPS scores < 45, ($p < 0.0003$, Fisher's exact test).</p> <p>Relationship: For veterans, only the SAT group significantly improved in DAS, ECR-R-avoidance, and ECR-R-anxiety at post-treatment ($p < 0.0002$, 0.0002, 0.004, respectively) and at FU ($p < 0.0001$, 0.0003, 0.006, respectively). Significant treatment*time interaction for DAS at post-treatment ($p < 0.007$) and FU ($p < 0.003$); and ECR-R-avoidance at post-treatment ($p < .03$).</p> <p>For spouses, only ECR-R-anxiety in the SAT group showed significant improvements at post-</p>	<p>combat experience</p> <p>Limitations: More than 50% of sample on psychotropic medication which may also account for decrease in PTSD symptoms over time</p> <p>Relatively short FU period</p>

Study number, author & year	Study aims and treatment type	Design, method and recruitment	N (n per condition/ phase)	Study and demographic information	Main outcome measures	Key findings and effect sizes	STROBE percentage criteria met & quality appraisal
				Ethnicity veteran: Caucasian (n= 37); Hispanic (n= 2); African American (n= 13); Asian/Pacific Islander (n= 2); American Indian/Alaska native (n= 2)		treatment ($p < 0.009$), and FU ($p < 0.006$). Significant treatment*time interaction effect for ECR-R–anxiety, SAT group exhibited significant improvement compared to PFE at post- treatment ($p < 0.04$) and FU ($p < 0.02$). No effect sizes calculated.	
				Ethnicity spouse: Caucasian (n= 41); Hispanic (n= 2); African American (n= 10); American Indian/Alaska native (n= 1)		Authors concluded efficacy of SAT in treating veteran PTSD whilst also improving relationship adjustment.	

Study number, author & year	Study aims and treatment type	Design, method and recruitment	N (n per condition/ phase)	Study and demographic information	Main outcome measures	Key findings and effect sizes	STROBE percentage criteria met & quality appraisal
9) Schumm, Fredman, Monson, and Chard (2013)	<p>1o: Assess effectiveness of Cognitive-behavioural conjoint therapy for PTSD in OEF-OIF veterans</p> <p>2o: Evaluate pre-treatment vs. post-treatment group effect sizes</p> <p>Treatment type: Disorder focused systemic couples therapy</p>	<p>Design: Uncontrolled trial</p> <p>Conditions: Within-group only Repeated measures: Baseline; post-treatment</p>	<p>N= 6 dyads</p> <p>Baseline: 6 dyads</p> <p>Post-treatment: 5 dyads (incomplete CAPS PTSD assessment of one veteran)</p>	<p>Country: USA</p> <p>Service: NES; OEF/OIF exposure.</p> <p>Status: NES</p> <p>Length relationship: \bar{x} 10.3 years (sd= 7.2)</p> <p>Age veteran: \bar{x} 37.2 years (sd= 7.2)</p> <p>Age spouse: \bar{x} 35.5 years (sd= 6.0)</p> <p>Education: NES</p>	<p>PTSD measures: Clinician Administered PTSD Scale (veteran)</p> <p>PTSD Checklist (both veteran and spouse's rating of veteran PTSD)</p> <p>Relational functioning measures: Dyadic Adjustment Scale (veteran and spouse)</p>	<p>PTSD:</p> <p>5/6 veterans met PTSD diagnostic criteria at baseline. 5/6 veterans scored below PTSD diagnostic criteria (CAPS) at post-treatment.</p> <p>Veterans showed reliable reductions in clinician-rated (4/5) or self-rated (5/6) PTSD symptom severity.</p> <p>At group level, significant reductions in PTSD as shown by CAPS ($p < 0.05$, $d = 1.51$), PCL-M ($p < 0.05$, $d = 1.43$) and partner rated PCL ($p < 0.05$, $d = 2.18$).</p> <p>Relationship: For veterans, at baseline 4/6 in non-distressed range, 5/6 in non-distressed range at post-treatment. 2/6 showed reliable improvement, 1/6 showed reliable worsening of symptoms.</p>	<p>Percentage criteria met: 86%</p> <p>Strengths: Limitations: Small sample size and uncontrolled design</p>

Study number, author & year	Study aims and treatment type	Design, method and recruitment	N (n per condition/ phase)	Study and demographic information	Main outcome measures	Key findings and effect sizes	STROBE percentage criteria met & quality appraisal
				Ethnicity: Caucasian (n= 10); Hispanic (n= 2)		For spouses, at baseline 3/6 were in non-distressed range, at post-treatment 6/6 were in non-distressed range. 3/6 showed reliable improvement. At group level for veterans, NS improvement ($d= 0.11$); for spouses, NS improvement ($d= 1.03$) Authors conclude reliable improvement in PTSD symptoms with corresponding large effect sizes, thus CBCT may reduce PTSD symptom severity in veterans.	
10) Schumm, Monson, O'Farrell, Gustin, and Chard (2015)	1o: Assess effectiveness of Couple Treatment for Alcohol Use Disorder and PTSD (CTAP) Treatment type: Disorder focused systemic	Design: Uncontrolled trial Conditions: Within-group only Repeated measures: Baseline; post-treatment (6 to 7 weeks)	N= 9 dyads Baseline: 9 dyads Post-treatment: 9 dyads (4 dyads completed all 15 sessions; 3 dyads attended 12 sessions; 2	Country: USA Service: NES; mixed conflict exposure Status: NES	PTSD measures: Clinician Administered PTSD Scale (veteran) PTSD Checklist- S (both veteran and spouse's rating of	PTSD: 6/9 veterans showed reliable improvement whilst 1/9 showed deterioration on CAPS; 6/9 showed reliable improvement on self-reported PCL-S; 7/9 showed reliable improvement on partner PCL-S. At group level, significant improvement on CAPS ($p = 0.028$, $d = 0.94$); self-reported PCL-S ($p =$	Percentage criteria met: 91% Strengths: Limitations: Small sample size and uncontrolled design

Study number, author & year	Study aims and treatment type	Design, method and recruitment	N (n per condition/ phase)	Study and demographic information	Main outcome measures	Key findings and effect sizes	STROBE percentage criteria met & quality appraisal
	couples therapy	later to put skills in place)	dyads attended 4 sessions then dropped out). Attrition rate: 25%	Length relationship: Range 1 to 31 years; 7 couples had cohabited < 9 years Age veteran: \bar{x} 42.2 years (sd= 16.1) Age: \bar{x} 39 years (sd= 12.6) Education: NES Ethnicity: Caucasian (n= 13); African American (n= 4); multiracial (n= 1)	veteran PTSD) Relational functioning measures: Dyadic Adjustment Scale (veteran and spouse)	0.009, $d = 1.22$; and partner PCL-S ($p = 0.001$, $d = 1.70$). Relationship: Reliable change on the DAS was mixed, with similar proportions improving versus showing no change or worsening. At group-level, NS improvement for veterans ($p = 0.482$, $d = 0.26$) and spouses ($p = 0.177$, $d = 0.52$). Authors concluded preliminary support for use of CTAP to reduce co-occurring problematic alcohol use and PTSD.	

Notes: 1° = Primary aim, 2° = secondary aim, 3° = tertiary aim

Effects sizes based on Cohen (1998). Strength of effect sizes as follows: Cohen's d and Hedge g - small 0.2, medium 0.5 and large 0.8; Partial eta squared (η_p^2)- small 0.01, medium 0.06 and large 0.14.

NS= Non-significant; FU= Follow-up; VAMC= Veteran Affairs Medical Centre; OEF= Operation Enduring Freedom (US led Afghanistan conflict 2001 to 2014); OIF= Operation Iraqi Freedom (US led Iraq conflict, 2003 to 2011); NES= Not explicitly stated; AD= Active duty; D= Discharged

Three studies reported follow-up periods varying between one to six months (studies 2, 3, 8).

Treatments

A range of couple-based interventions were identified: a) sport and recreation: “Higher Ground” program (study 1); b) complementary and alternative medicine (CAM): “Mission Reconnect” (study 2); c) retreats or courses: 5-day Lifestyle Management course (study 3); couple based psychosocial debriefing (study 4); d) three types of disorder focused systemic couples therapy: 1) cognitive behavioural approach for PTSD: Cognitive Behavioural Couples Treatment (CBCT; study 5, 9); 2) behavioural marital therapy for PTSD: Strategic Approach Therapy (SAT; study 6, 7, 8); and 3) combined behavioural marital and cognitive behavioural for PTSD and alcohol use disorder (CTAP; study 10).

Participants

All studies were US except study 3 which was Australian. Total number of participants was 622 (267 dyads), consisting of $n=343$ veterans and $n=279$ spouses; two studies contained samples higher in veterans (study 3 and 4). Two studies did not report gender (study 1 and 4), however males represented the majority of veterans in that only $n=6$ were female veterans. The majority of studies did not report service make-up (study 3, 5, 6, 7, 8, 9, 10), study 1 was mixed and study 2 and 4 were National Guard/Reserves. Similarly, the majority of studies (study 1, 3, 5, 6, 8, 9, 10) did not explicitly state if military participants were active duty or discharged. Two studies (study 2 and 4) consisted of military participants who were active duty reserve personnel ($n=82$), whilst study 7 consisted of discharged veterans ($n=6$). Mean length of relationship was 19.52 years (from four studies; study 5, 6, 7, 9), $sd=7.7$ (from study 9). Mean veteran age was 44 years (from 9 studies; study 4 did not report age), $sd=8.6$ (from six studies; study 2, 3, 6, 8, 9, 10), mean spouse age was 36.34 years (from nine studies; study 4 did not report age), $sd=7.98$ (from six studies; study 2, 3, 6, 8, 9, 10). Study 2 and 8 reported education: some high school $n=22$; high school graduate $n=31$; some college $n=85$; technical school $n=16$; BA $n=37$; MA $n=6$; PhD/MD $n=2$. Eight studies reported ethnicity (study 3 and 4 did not): Caucasian $n=227$; African American $n=43$; Hispanic $n=19$; American Indian/Alaska Native $n=7$; mixed race

n= 3; Native Hawaiian/Pacific Islander n= 2 which suggested ethnic minorities were under-represented.

Measures

Three measures were used to assess PTSD outcome and eight measures were used to assess relational functioning outcome. All PTSD and relational functioning measures had Cronbach's alpha above the cut-off of .70 indicating outcome measures used in the included studies were of acceptable internal consistency (Cortina, 1993). Alphas ranged from acceptable (>.70) to excellent (>.90). See Appendix B for full details.

Quality Appraisal

The percentage of quality criteria met on the STROBE ranged from 59% to 95%. Only three studies met 90% or more of the criteria (study 3, 8, 10), four studies met between 80 to 90% (study 2, 5, 6, 9), two studies met between 70 to 80% (study 1, 7), whilst study 4 met 59% of criteria. Main weaknesses were a) studies not providing details on power (only study 3 reported obtained power), b) small sample sizes (study 1, 5, 6, 7, 9, 10 ≤ 17 dyads), c) five studies did not report effect sizes (study 1, 2, 4, 7, 8), and d) two studies did not correct for multiple testing possibly resulting in Type 1 errors (study 2 and 4).

Strengths: Study 3, 5, 6, 9, 10 reported individual-level change using reliable change criteria (Jacobson & Truax, 1991).

Review Question

PTSD.

Ten studies reported veteran PTSD outcomes. Nine reported significant reductions in symptoms over time on either clinician, self-report measures or partner's ratings of veteran symptoms (study 1, 2, 4, 5, 6, 7, 8, 9, 10). Of these nine studies, treatments encompassed the full range identified across all included studies: retreat; CAM, sports and recreation as well as disorder focused systemic couples therapy. Only five studies reported effect sizes which ranged from small to large (study 3, 5, 6, 9, 10); the small effect size was associated with course treatment type (study 3), whilst all medium to large effect sizes were associated with the three disorder focused systemic couples therapy (study 5, 9: CBCT, study 6: SAT and study 10: CTAP). Two non-randomised controlled trials showed

significantly greater symptom reduction in all treatment compared to control groups over time (study 1 and 4) as well as a significant treatment*time interaction favouring the treatment group (study 4). The percentage of STROBE quality criteria met within these nine studies ranged from 59 to 95%, i.e., encompassed the full range of quality ratings identified in all ten included studies. However, six of these nine studies used a small sample size, i.e., study 1, 5, 6, 7, 9, 10 consisted of ≤ 17 dyads. Only one of the nine studies included the “gold standard” RCT research design (study 8). Furthermore, two studies did not correct for multiple testing possibly resulting in Type 1 errors (study 2 and 4). For example, in study 2, if an adjusted p value of 0.0025 was used then the PTSD findings would be non-significant. Likewise, in study 4, using an adjusted p value of 0.007, the main effect of treatment for PTSD intrusive deployment stressor and the treatment*time interaction for PTSD avoidance post deployment would be non-significant. Study 3 reported non-significant reductions (small effect sizes) in symptoms over time. Arguably, study 3 was one of the higher quality studies in that it met 95% of STROBE quality criteria, was the only included study to report details on power and consisted of the largest sample size of all included studies (98 dyads). However, a methodological flaw of this study was its within-group uncontrolled design. Based on combined clinician, veteran self-report and partner ratings, five studies revealed the mean reliable improvement was 75% ($sd = 22$), 3.5% ($sd = 5.7$) showed reliable deterioration (study 3, 5, 6, 9, 10).

Study 3 reported on spouse PTSD (i.e., secondary traumatization) and found a significant reduction in symptoms at four and eight week follow-up.

Relational functioning.

Overall, all but one study (study 7) reported outcomes on relational functioning. Studies 1 and 4 reported combined veteran and spouse outcomes. Study 1 reported a significant increase over time in the treatment group (program plus communication). Study 4 reported non-significant main effects of time and group and a significant treatment*time interaction of increased relational functioning over time in the treatment group. However the size of the effects in study 1 and 4 were not reported.

Seven studies reported veteran outcomes, of which only study 8 showed significantly increased relational functioning. Specifically, in the treatment

condition at post treatment and 12 week follow-up alongside a significant treatment*time interaction favouring the treatment group. Study 8 was one of the higher quality studies in that it met 95% of STROBE quality criteria, consisted of the second largest sample size of all included studies (57 dyads) as well as used the “gold standard” RCT research design. Five studies reporting small to medium effect sizes failed to find significant improvements in relational functioning over time (study 2, 3, 6, 9, 10). Three of these studies (study 6, 9, 10) consisted of small sample sizes (≤ 17 dyads) and used a less robust within-group uncontrolled research design. No studies reported significant deterioration in relational functioning over time, although study 5 showed a small effect in worsening relational functioning. Study 5 consisted of only seven dyads and used a within-group uncontrolled research design. Four studies revealed 34% (sd= 29) had reliably increased in relational functioning whilst 21% (sd= 6.6) showed a reliable deterioration (study 5, 6, 9, 10).

Seven studies reported spouse relational functioning. Significant findings of increased relational functioning mirrored veterans' reporting above (study 8). Six studies reporting small to large effects failed to find significant increases over time (study 2, 3, 5, 6, 9, 10). Four studies revealed 49% (sd= 6.5) had reliably improved in relational functioning whilst 6% (sd= 7.3) showed a reliable decrease (study 5, 6, 9, 10).

Discussion

This review systematically examined evidence for the effectiveness of couple based interventions for PTSD and relational functioning in military couples. A wide range of couple based interventions were identified: sports and recreation activities, CAM and retreats. Six studies reported on more traditional and structured couple based therapies (CBCT, SAT and CTAP).

Nine of the ten included studies reporting veteran PTSD demonstrated significant reductions in symptoms as reported by clinician, self-report or partner rating. The five studies that reported reliable individual-level change data showed mean reliable improvement in 75% of veteran samples; these same five studies showed small to large effect sizes. Of these five studies, the three disorder focused systemic couples therapies showed medium to large effect sizes. SAT and CTAP were consistently associated with large effect sizes across clinician,

self-report and partner ratings. Overall, couple based interventions demonstrated support for treating PTSD. Based on reported effect sizes, reliable change indexes and theoretical foundation, there was relatively stronger evidence to support disorder focused systemic couple therapies over sport and recreation activities, CAM and retreats/courses. However, these findings must be interpreted with caution for the following reasons: a) all but one of the nine studies that showed significant differences used relatively less robust designs, i.e. non-randomised controlled trials or within-group uncontrolled trials; b) two studies possibly reported Type 1 errors for PTSD outcomes on the basis of failure to reject true null hypotheses due to not correcting for multiple testing; and c) six of nine studies used a small sample size (i.e. ≤ 17 dyads). For the latter point, it would appear some authors recognised the limitation of a small sample and consequently underpowered findings, thus reliable individual-level change data were reported (Devilly et al., 2002; Monson et al., 2004; Sautter et al., 2014; and Schumm et al. 2013, 2015). Whilst there was evidence of overall support for couple based interventions in treating PTSD, in particular disorder focused systemic couples therapies, it was also apparent studies investigating couple interventions for PTSD lack robust designs.

All but one study reported relational functioning outcomes. Overall, there was little support for beneficial effects of relational functioning with only three of nine studies reporting significantly improved relational functioning following couple based treatment (Bennett et al., 2014; Ford et al., 1993; Sautter et al., 2015). These three studies encompassed a range of treatment types: sports and recreation program (Bennett et al.), a psychosocial course (Ford et al.) and the couple based therapy SAT (Sautter et al., 2015). Only the latter study was rated as a higher quality study in that it met 95% of quality criteria whilst the former two studies were relatively poorer rated studies (59%/77% of quality criteria were met, respectively). Furthermore, Bennett et al. and Ford et al. reported combined veteran and spouse findings, thus it is difficult to determine whether the effect would be the same for both parties.

It should also be noted the trend for improved relational functioning was relatively stronger for spouses, in that the seven studies that reported this outcome all showed ratings that ranged from small to large effect sizes. Four studies (Monson et al., 2004; Sautter et al., 2014, Schumm et al., 2013, 2015)

reported mean reliable improvement in 49% of spouses whilst 6% showed a reliable deterioration in their relationship. In contrast, six of seven studies reporting relational functioning by veterans showed only small effect sizes, whilst one study reported a deterioration. In line with this, four studies revealed 34% reported a reliable improvement in relational functioning whilst 21% had reliably deteriorated (Monson et al., 2004; Sautter et al., 2014, Schumm et al., 2013, 2015). The discrepancy may be due to high pre-treatment relational functioning ratings i.e. ceiling effect, thus little scope for improvement (veterans: Schumm et al., 2013, 2015; spouses: Sautter et al., 2015). Alternatively, adjustment to post-therapy relationship narratives and subsequent changes in perception of relationship quality may lag reductions in PTSD symptoms. Longer follow-up periods may be required in order to capture this effect. On balance, based on study quality, effect sizes and reliable change indexes, there was relatively stronger evidence of improved relational functioning from disorder focused systemic couple therapies, in particular SAT, over sport and recreation activities, CAM and retreats/courses.

Females and ethnic minorities were under-represented, yet literature suggests these factors need consideration. Understanding the nature of the traumatic event is important given PTSD in female veterans is largely associated with sexual assault whilst in the military, whereas it is combat exposure for males (Middleton & Craig, 2012). Ethnic minority status in veterans undergoing PTSD treatment was associated with weaker therapeutic alliance (Koo, Tiet, & Rosen, 2015), thus a diversity-informed conceptual framework may be helpful (Loo, Singh, Scurfield, & Kilauano, 1998). Also of note, only two of ten studies explicitly stated whether the military participants were active duty or discharged. However, the US definition of “veteran” is on the basis of completion of a minimum period of military service (Szymendera, 2016). Since all but one study was from the US, it is assumed participants were discharged unless otherwise stated.

Comparison to other psychosocial intervention literature in military populations

Two systematic reviews exist for individual and group based psychosocial therapies for PTSD. Kitchiner et al. (2012) meta-analysis of four studies (N= 128) showed some evidence for the efficacy of trauma focused therapies (standard

mean difference= -0.59, 95% CI -1.09, -0.10, favouring individual based trauma focused psychosocial interventions vs. usual care or waiting list). Steenkamp et al. (2015) reviewed nine RCTs (N= 883) revealing large within group post treatment effect sizes (Cohen's *d* range, 0.78-1.10) for cognitive processing and prolonged exposure therapies. Steenkamp et al. concluded there was support for the use of trauma focused or structured non-trauma focused therapies in PTSD, but also a need to improve existing treatments and test novel evidence based treatment strategies given high non-response and dropout rates. Neither review included couple based interventions in their meta-analyses. Compared to the above reviews, this review provides preliminary support for the use of couple based interventions in the treatment of PTSD, in particular disorder focused systemic couple therapies, with comparable effect sizes and reliable change indices to individual and group based treatments. However, couple based intervention research is still in its infancy as only one RCT has exclusively focused on treating PTSD (Sautter et al., 2015).

A scoping review suggests an emerging evidence base for CAM. However, intervention studies were generally poor quality and no effectiveness data were reported (Elwy, Johnston, Bormann, Hull, & Taylor, 2014). A narrative review of sport and physical activity studies with veterans highlighted positive effects on emotional and psychological well-being, yet no RCTs were identified (Caddick & Smith, 2014). Yosick et al. (2012) cite a wide range of programmes aimed at reintegration for veterans yet the authors state there was no consensus on how to define or evaluate reintegration resources. CAM, sport and retreat based interventions are encouraging in light of recommendations by Steenkamp et al. (2015). However, their overall strength of evidence is limited by lack of either robust research designs or theoretical foundation. This is a relative weakness compared to included studies in this review based on either systemic or cognitive behavioural theoretical models (Monson et al., 2004; Sautter et al., 2009, 2014, 2015; Schumm et al., 2013, 2015), or that used a robust study design (Sautter et al., 2015).

Strengths and weaknesses of review

Strengths include the wide number of databases searched, the use of a thorough quality appraisal tool and following the Preferred Reporting Items for

Systematic reviews and Meta-Analyses (PRISMA) Statement guidelines at all review stages (Moher, Liberati, Tetzlaff, & Altman, 2009). The main limitation was the lack of meta-analyses due to heterogeneity of study designs, investigated interventions and unequal treatment durations.

Future directions- research and clinical

This review highlights the lack of robust designs used in effectiveness research of couple based interventions in military populations; only one RCT met review inclusion criteria. Quality appraisal revealed methodological flaws in many included studies, e.g., small sample sizes leading to underpowered studies or not correcting for multiple testing. Future studies would benefit from following reporting guidelines such as the STROBE checklist in order to improve their methodological quality. In addition, the majority of included studies were uncontrolled trials thus it would be beneficial to conduct methodologically rigorous RCTs in future.

Within the USA, recent policies by the Office of Mental Health Services and the Veteran Affairs system recommend nationally available training for clinicians in empirically based couple therapy (Makin-Byrd et al., 2011). In contrast, only two UK surveys on relationship factors in UK military personnel exist. Rowe, Murphy, Wessely, and Fear (2012) reported amongst other factors, veteran's mental health predicted relationship dissolution and Keeling, Wessely, Dandeker, Jones, and Fear (2015) showed veteran childhood adversity and limited support for and from family predicted partner relationship dissatisfaction. UK studies report PTSD prevalence rates between 1.3% to 4.8% (Hotopf et al., 2006; Iversen et al., 2009; Rona et al., 2006). In line with the framework for complex interventions (Medical Research Council, 2000), this review serves as a pre-clinical phase highlighting potential for couple based interventions to be effective in treating PTSD symptoms in the UK military. Further research is required to investigate the acceptability of couple based interventions in UK military personnel and veterans, followed by exploratory trials and definitive RCTs.

Conclusion

There is preliminary evidence based mainly on observational studies of support for couple based interventions treating PTSD. Based on reported effect

sizes, reliable change indexes and theoretical foundation, there was relatively stronger support for disorder focused systemic couple therapies over sports and recreation activities, CAM and retreats/courses. There was relatively little support for improved relational functioning in couple based interventions treating PTSD. However, spouses tended to report a greater degree of improved relational functioning compared to veterans. Whilst effect sizes were cautiously comparable with RCTs of individual or group based PTSD psychotherapies, only one couple based RCT PTSD intervention met inclusion criteria. Robust RCTs of couple based interventions are now needed in the USA, as well as encouraging clinicians and researchers working with UK military veterans to consider the use of this intervention.

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Appendix A: Form used for data extraction and quality appraisal (STROBE: Qualitative Appraisal Tool for Studies in Epidemiology)

Authors:

Title:

Criteria met:

1	TITLE & ABSTRACT	(a) Indicate the study's design with a commonly used term in the title or the abstract	Criteria met?
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Yes/No
			a) b)
	INTRODUCTION		
2	Background/ Rationale	Explain the scientific background and rationale for the investigation being reported	Criteria met?
			Yes/No
3	Objectives	State specific objectives, including any pre-specified hypotheses	Criteria met?
			Yes/No
	METHODS		
4	Study design	Present key elements of study design early in the paper	Criteria met?
			Yes/No

5	Setting	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Criteria met? Yes/No
6	Participants	(a) Cohort study—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up Case-control study—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants (b) Cohort study—For matched studies, give matching criteria and number of exposed and unexposed Case-control study—For matched studies, give matching criteria and the number of controls per case	
7	Variables of interest	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Criteria met? Yes/No
8	Measurement	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Criteria met? Yes/No
9	Bias	Describe any efforts to address potential sources of bias	Criteria met? Yes/No

10	Sample size	Explain how the study size was arrived at	Criteria met? Yes/No
11	Quantitative variables	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	Criteria met? Yes/No
12	Statistical methods	<p>(a) Describe all statistical methods, including those used to control for confounding</p> <p>(b) Describe any methods used to examine subgroups and interactions</p> <p>(c) Explain how missing data were addressed</p> <p>(d) Cohort study—If applicable, explain how loss to follow-up was addressed</p> <p>Case-control study—If applicable, explain how matching of cases and controls was addressed</p> <p>Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy</p> <p>(e) Describe any sensitivity analyses</p>	Criteria met? Yes/No
			<p>a)</p> <p>b)</p> <p>c)</p> <p>d)</p> <p>e)</p>
	RESULTS		

13	Participants	<p>(a) Report the numbers of individuals at each stage of the study—e.g., numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed</p> <p>(b) Give reasons for non-participation at each stage</p> <p>(c) Consider use of a flow diagram</p>	<p>Criteria met?</p> <p>Yes/No</p>
			<p>a)</p> <p>b)</p> <p>c)</p>
14	Descriptive data	<p>(a) Give characteristics of study participants (e.g., demographic, clinical, social) and information on exposures and potential confounders</p> <p>(b) Indicate the number of participants with missing data for each variable of interest</p> <p>(c) Cohort study—Summarise follow-up time (e.g., average and total amount)</p>	<p>Criteria met?</p> <p>Yes/No</p>
			<p>a)</p> <p>b)</p> <p>c)</p>
15	Outcome data	<p>Cohort study—Report numbers of outcome events or summary measures over time</p> <p>Case-control study—Report numbers in each exposure category, or summary measures of exposure</p> <p>Cross-sectional study—Report numbers of outcome events or summary measures</p>	<p>Criteria met?</p> <p>Yes/No</p>
16	Main results	<p>(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included</p> <p>(b) Report category boundaries when continuous variables were categorized</p>	<p>Criteria met?</p> <p>Yes/No</p>

		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
			a) b) c)
17	Other analyses	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	Criteria met? Yes/No
	DISCUSSION		
18	Key findings	Summarise key results with reference to study objectives	Criteria met? Yes/No
19	Limitations	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Criteria met? Yes/No
20	Interpretation	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Criteria met? Yes/No

21	Generalisability	Discuss the generalisability (external validity) of the study results	Criteria met? Yes/No
22	Funding	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Criteria met? Yes/No

Appendix B: Summary of outcome measures used by included studies

Domain	Outcome measure and reference	Brief description
PTSD	PTSD Checklist- Civilian or Military (Weathers, Litz, Herman, Huska, & Keane, 1993)	PCL-C is a 17-item self- report scale that assesses the Diagnostic and Statistical Manual for Mental Disorders 4 th edition (DSM-V; American Psychiatric Association, 2000) diagnostic symptoms of PTSD using a 5-point Likert scale (1= not at all to 5=extremely), score range from 17 to 85. Three versions of the PCL- checklist are available. The PCL-M is a military version and questions refer to “a stressful military experience”. The PCL-S is a non-military version that can be referenced to any specific traumatic event; the questions refer to “the stressful experience”. The PCL-C is a general civilian version that is not linked to a specific event; the questions refer to “a stressful experience from the past”. Scoring is the same for all three versions. Cronbach's alpha ranged from .94 to .97 (Blanchard, Jones-Alexander, Buckley, & Fomerls, 1996; Weathers et al., 1993).
	Impact of Events Scale (Horowitz, Wilner, & Alvarez, 1979)	15-item questionnaire evaluating experiences of avoidance and intrusion which attempts to “reflect the intensity of the post-traumatic phenomena” (McGuire, 1990). There are 7 intrusion items (e.g., nightmares, flashbacks) and 8 avoidance/numbing items (e.g., alexithymia, avoidance of stimuli associated with stressors) for symptoms experienced during the past week. Cronbach's alpha for intrusion scale .79; avoidance scale .82.

	Clinician Administered PTSD Scale (Blake et al., 1995)	Semi-structured clinician interview that measures PTSD diagnostic status and symptom severity consistent with DSM-V criteria for PTSD (American Psychiatric Association, 2000). Higher scores indicate greater symptoms severity with scores ranging from 0 to 136. Internal consistency for intensity of PTSD symptom criteria was examined in a sample of 25 veterans (Blake et al., 1990). Cronbach's alpha ranged from .73 to .85. Internal consistency was also high within a sample of older veterans, .87 to .95 (Hyer, Summers, Boyd, Litaker, & Boudewyns, 1996).
Relationship satisfaction	Abbreviated Dyadic Adjustment Scale (Sharples & Rogers, 1984)	7-item self-report scale derived from the 32-item Spanier (1976) Dyadic Adjustment Scale. Cronbach's alpha = .76.
	Compassionate Love Scale (Sprecher & Fehr, 2005)	21 item self-report scale with a single score that assesses compassionate or altruistic love. Items scored on a 7-point Likert scale (1= not at all true of me to 7= very true of me). Cronbach's alpha = 0.95.
	Dyadic Adjustment Scale (Spanier, 1976)	32-item self-report inventory designed to measure satisfaction in intimate dyads. Score range is 0 to 151, scores <100 represent the dissatisfied range. Cronbach's alpha =.96.
	Experiences in Close Relationship-Revised (Fraley, Heffernan, Vicary, & Brumbaugh, 2011)	10-item self-report measure designed to assess attachment orientation across four kinds of intimate relationships (i.e., relationships with mother, father, romantic partners, and best friends). The same 10 items are used for each domain, yielding 40 items total. Items scored on a

	7-point Likert scale (1= <i>strongly disagree</i> ; 7= <i>strongly agree</i>). Measure provides anxiety and avoidance subscale, and a global score. For the anxiety sub-scale, the alpha reliabilities across four relationships were .84, .87, .83, and .83, respectively. For avoidance sub-scale, the alpha reliabilities across four relationships were .91, .92, .81, and .85, respectively.
Family APGAR (Smilkstein, 1980)	5-item inventory assessing perceptions of family support in the domains of adaptation, partnership, growth, affection, and resolve. Cronbach's alpha was .85 (Gardner et al., 2001).
Locke Wallice Marital Adjustment Scale (Locke & Wallace, 1959)	16 item self-report scale scored on varying scales. A score of 100 is the dividing point between distressed and non-distressed individuals, scores >100 indicating greater marital satisfaction. Cronbach's alpha = .83 (Cross & Sharpley, 1981).
Relationship Adjustment Scale (Hendrick, 1988)	7 item self-report scale of general satisfaction within a relationship. Cronbach's alpha ranging from .86 to .93.
Revised Dyadic Adjustment Scale (Busby, Christensen, Crane, & Larson, 1995)	15 item self-report scale scored on a 6-point Likert scales (1= always disagree to 6= always agree) produces a total score range 15 to 90, higher scores indicating more marital satisfaction. Cronbach's alpha = .90.



SCHOOL OF PSYCHOLOGY

DOCTORATE IN CLINICAL PSYCHOLOGY

EMPIRICAL PAPER

The association between maladaptive emotion regulation and cause of injury in UK military veterans with co-occurring TBI and PTSD

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Abstract

Objective: Deployment to the armed conflicts in Afghanistan (Operation HERRICK/Enduring Freedom) and Iraq (Operation TELIC/Iraqi Freedom) can adversely affect the physical and mental health of those deployed. This study explored the association between traumatic brain injury (TBI), post-traumatic stress disorder (PTSD), the mediating effect of maladaptive emotional regulation strategies (MERS) and the effect of cause of injury (no injury, blunt force related or blast force related) in UK military veterans.

Methods: 16 month longitudinal follow-up was conducted on a sample of 123 veterans (Murphy et al., 2015). Regression based secondary data analyses investigated the mediating effects of MERS (n=116) whilst correlational analyses explored the effect of injury mechanism on the relationship between TBI severity and PTSD severity (n=29).

Results: Findings revealed support for the role of anger in mediating the effect that TBI severity had on PTSD severity. There was no support that the mechanism of injury was associated with greater reporting of psychological symptoms (anger, alcohol use or PTSD) or that MERS influenced the association between TBI severity and PTSD recovery at 16 month follow-up.

Conclusion: Findings contribute to the understanding of how anger may underlie the relationship between TBI severity and PTSD severity, i.e., TBI severity was positively associated with PTSD scores and this effect operated due to increased TBI severity leading to higher rates of expressed anger which in turn increased PTSD symptoms. Future research using larger samples is required to further understand how the complicating factors of MERS and cause of physical injury affect outcome in veterans with co-occurring TBI and PTSD.

Introduction

Military deployment can tremendously impact the physical and mental health of those deployed⁴. The Afghanistan and Iraq conflicts present unique challenges: a) prolonged or multiple tours (Bruner, 2006) and thus increased likelihood of combat engagement (Hoge, Castro, Messer, McGurk, Cotting & Koffman, 2004), b) increased survivability due to advances in medicine and head/body armour (Tanielian & Jaycox, 2008), and c) the high degree of blast-related injuries (Jones, Fear & Wessely, 2007; Owens, Kragh, Wenke, Macaitis, Wade & Holcomb, 2008). Combined, these factors increase risk of physical trauma, e.g., traumatic head injury (TBI) and psychological disorders, e.g., post-traumatic stress disorder (PTSD) compared to non-deployed military personnel (e.g., Prigerson Maciejewski & Rosenheck, 2002). It is therefore important to understand the unique association between exposure to blast trauma, TBI, PTSD and recovery.

Traumatic brain injury (TBI)

TBI is defined as a blow to the head or a penetrating head injury that disrupts brain function (Martin, Farris, Parker & Epley, 2010). Severity ranges from mild, a brief change in mental status with or without loss of consciousness (LOC) to severe, an extended period of unconsciousness or amnesia following injury. Mild TBI (mTBI) has regularly been cited as a characteristic injury of the Afghanistan and Iraq conflicts (Jones et al., 2007), yet the prevalence rate varies depending on study origin. In US military personnel, rates range from 8% (Vasterling et al., 2006) to 40% in those exposed to a blast (Okie, 2005). A study conducted in the UK forces by Rona et al. (2012) reported mTBI prevalence was 4.4% and 9.5% in those with a combat role.

⁴ The following terms are often used to describe military populations: 'veteran', 'combat veteran', 'war veteran', 'injured service member', 'military personnel', and 'ex-military personnel'. However, none of them are clearly defined (Burdett et al., 2012). For the purpose of this study, the term 'veteran' will be used to describe former serving members of the armed forces, 'military personnel' will be used to describe active duty personnel, whereas 'military populations' encompasses both, unless otherwise stated.

Cause of head injury.

Improvised explosive devices in the Afghanistan and Iraq conflicts have resulted in 78% of all injuries in US service members being blast-related (Jones et al., 2007; Owens et al., 2008). Rona et al. (2012) reported blast injuries as the most frequent injury mechanism of mTBI in UK military personnel. Blast injuries are characterised by shock or pressure waves transiting the skull and body and rapid acceleration/deceleration forces thus soft tissue such as the brain may be particularly vulnerable (e.g., Ling, Bandak, Armonda, Grant & Ecklund, 2009). Whilst the mechanism of injury substantially differs between blast and blunt force related injuries, there is debate as to whether there are differences in outcomes from these mechanisms. For example, patients with blast related vs. non-blast related mTBI have been shown to have similar cognitive and symptomatic outcomes regardless of injury mechanism (Luethcke et al., 2011, Belanger et al., 2009, Belanger et al., 2011, Wilk et al., 2010). In a cohort study of UK military personnel, presence and severity of post-concussion syndrome (PCS) was associated with blast mTBI as well as non-blast related incidents such as aiding wounded personnel, suggesting PCS was non-specifically related to mTBI (Fear et al., 2009a). In a cohort study of US military personnel, those with blast related mTBI and LOC were significantly associated with presence of headaches and tinnitus whereas those reporting blast related mTBI without LOC were not associated with adverse health outcomes, leading the authors to conclude that blast mechanism was inconsistently associated with PCS (Wilk et al., 2010). A review by Cernak and Noble-Haeusslein (2010) concluded much of the literature was contradictory and often misleading due to misunderstanding the complexities of blast injuries and shockwave physics. Margulies and Hicks (2009) concluded from their review that many of the early pathobiological events seen in experimental animal models of TBI (such as vasospasm and EEG abnormalities) were also found in human studies of blast TBI as well as the lack of strong evidence that blast was categorically different from other TBI mechanisms.

However, there does exist evidence to the contrary regarding self-reported psychological symptoms. For example, veterans with blast related mTBI have been shown to exhibit a greater degree of neuroticism, anger, frustration, toughness and boundary violations (Mendez, Owens, Jimenez, Peppers & Light, 2013) compared to non-blast related mTBI injured veterans. Bolzenius, Roskos,

Salminen, Paul and Bucholz (2015) report veterans with blast related mTBI scored significantly higher on self-ratings for depressive, anxious and somatic symptoms than civilians with non-blast related mTBI, independent of PTSD diagnosis. A review by Rosenfeld and Ford (2010) concluded that whilst blast related concussion (vs. non-blast related) may have more psychological sequelae and a stronger association with PTSD, there was emerging evidence that parts of the brain injured in blast TBI were concerned with regulation of emotions and judgement and this organic component of brain injury may contribute to the onset of PTSD and depression. Thus exposure to a blast was unlikely to cause PTSD and depression by psychogenic means alone. Levin et al. (2010) conducted diffusion tensor imaging and assessment of PCS, PTSD, depression and health related quality of life in veterans with blast related TBI and a comparison group of both non-blast extracranial injured veterans and non-injured veterans. Whilst findings showed no between group differences in the integrity of white matter microstructure, significantly higher rates of PCS (specifically physical, cognitive and sensory symptoms but not affective symptoms), PTSD, emotional distress and depression were found in those with blast related TBI compared to the comparison group.

Simmons & Mathews (2012) reviewed functional magnetic resonance imaging studies to investigate the overlap in neural correlates between PTSD and mTBI. Mild TBI was generally associated with dysregulated functional activation in several prefrontal, parietal and temporal regions (superior and middle frontal gyri, superior and inferior parietal lobules and superior temporal gyrus) that are involved in decision making and self-control as well as the medial frontal cortex, which is involved in self-referential processing and is a central component of the default mode network of the brain. Regarding PTSD, the amygdala, anterior cingulate and the middle frontal gyrus were differentially activated between PTSD and non-PTSD individuals. The main findings of region overlap between mTBI and PTSD studies were noted in the middle frontal gyrus, an area often associated with processes such as set-shifting both in cognitive and emotional tasks. Hoffman and Harrison (2009) report the prefrontal regions as being more susceptible to damage from blasts which may be important in the comorbidity of PTSD and mTBI. Exposure to a blast related TBI during a traumatic event can lead to a flood of stress hormones that impair the cerebral structures involved in

the control of fear and anxiety thus leading to limited recovery. This is in line with neural models of PTSD that postulate PTSD symptoms are related to ineffective “top-down modulation” of the amygdala and limbic circuitry by the prefrontal cortex (Liberzon & Sripada, 2008; Shin et al., 2006). This has been implicated as an underlying mechanism for the depersonalization seen in PTSD (Sierra & Berrios, 1998; Lanius et al., 2002). Taken together, these findings suggest that frontal lobe dysfunction, regions associated with the regulation of emotions and judgement, can cause both cognitive and emotional sequelae by reducing the capacity to adapt to environmental change and may constitute a biological mechanism towards PTSD onset. Given involvement of these frontal brain areas, it is plausible blast trauma has specific detrimental impact on an individual’s ability to cognitively and affectively process the traumatic event and to regulate associated emotions appropriately.

There is an emerging pattern of evidence that there are differences in outcome between non-blast related TBI and blast related TBI. Specifically, objective, cognitive assessments suggest similar levels of functioning and recovery from these two causes of injury whereas subjective psychological symptom reporting indicates elevated levels associated with blast TBIs compared to non-blast TBIs. Furthermore, no study to date has investigated the role that cause of injury has on psychological functioning in UK military personnel; Fear et al. (2009a) investigated the role of cause of injury on PCS but did not specially explore whether injury mechanism influenced psychological symptoms of PTSD. Given US findings of differential psychological symptoms in response to blast vs. blunt force injuries, if findings were replicated in UK samples this may have screening and treatment implications. PTSD should also be considered since TBIs can often occur under traumatic circumstances.

Post-traumatic stress disorder (PTSD)

PTSD can develop following a traumatic event (American Psychiatric Association [APA], 2013). PTSD prevalence rates in UK military studies range between 1.3% to 4.8% at one to two years post-deployment (Hotopf et al., 2006, Iversen et al., 2009; Rona et al., 2006), whilst US studies report rates up to 17% one year post-deployment (Hoge, Terhakopian, Castro, Messer & Engel, 2007). Ramchand, Karney, Osilla, Burns and Caldarone (2008) reported combat duty

and being wounded were consistently associated with a positive PTSD screen, regardless of study origin, assessment measure or time.

Long term impact.

Evidence suggests a greater degree of delayed onset PTSD in veterans compared to general population rates (30% vs. 15%, respectively; Andrews, Brewin, Philpott and Stewart, 2007; NICE, 2005). Hoge et al. (2007) reported military personnel with PTSD was associated with poorer health outcomes, e.g., poorer general health and increased somatic complaints compared to those without PTSD, independent of presence of injury. However, injury type (e.g. head or non-head injury) and cause (e.g. blunt or blast injury) and their associations with health outcomes remains unknown. For instance, greater somatic symptom severity may represent a distress reaction in blast vs. non-blast injured personnel.

TBI and PTSD in military personnel

TBI and PTSD can co-occur in military populations and are seen as signature injuries of the Afghanistan and Iraq conflicts (Okie, 2005; Warden, 2006). Incidence studies of TBI and PTSD amongst US military personnel have found higher rates of psychological and medical problems compared to the general population (Hoge et al., 2004). Hoge et al. (2008) revealed a dose-response relationship between mTBI and presence of PTSD symptoms. Rates ranged from 9.1% in non-injured personnel, 16.2% with other injuries, 27.3% in mTBI with altered mental state (AMS) to 43.9% in mTBI with LOC. A history of single concussion was positively associated with symptoms of PTSD, depression and anger, whereas multiple lifetime concussions increased this relationship alongside increased PCS symptoms (Spira, Lathan, Bleiberg & Tsao, 2014). In UK armed forces, Jones et al. (2014) reported PTSD severity was significantly associated with reporting mTBI and mTBI with symptoms. Rona et al. (2012) found presence of mTBI was associated with current PTSD symptoms (AOR= 5.2), alcohol misuse (AOR= 2.3) and multiple physical symptoms (AOR= 2.6).

In summary, PTSD in military personnel may occur under at least three contexts: a) psychological trauma experienced during deployment may be processed maladaptively and lead to PTSD; b) physical trauma during deployment may lead to PTSD; c) alternatively, a traumatic event may give rise

to both TBI and trigger PTSD, thus leading to relatively poorer outcome compared to those without TBI. However, Hoge et al. (2008), Rona et al. (2012) and Jones et al. (2014) report only descriptive statistics on cause of injury, i.e., there were no analyses that investigated the association between cause of injury and reported symptoms. Thus it remains unknown if the cause of injury may influence the type and severity of reported symptoms. Further research is needed to understand the links between cause of injury, emotional resources and outcome.

Emotional regulation: A “lynchpin” function between TBI and PTSD?

Emotional regulation is “the process by which individuals influence which emotions they have, when they have them, and how they experience and express these emotions” (Gross, 1998, p. 275). A history of TBI has been associated with an increased risk of problems with the recognition, experience, expression and control of anger compared to non-injured counterparts in civilians (Dethier, Blairy, Rosenberg & McDonald, 2013) and military personnel (Bailie et al., 2015). Reviews show PTSD severity is strongly positively associated with anger, this association being greater in veterans vs. civilians (Orth & Wieland, 2006; Taft, Watkins, Stafford, Atreeta & Monson, 2011). Despite evidence linking anger and PTSD, the underlying mechanisms remain poorly understood (Beckham, Moore & Reynolds, 2000). A key issue in understanding the pathogeny and diagnosis of PTSD is the role of anger. The diagnostic criteria of PTSD lists irritability and outbursts of anger as one of the hyperarousal symptoms (Diagnostic and Statistical Manual of Mental Disorders [DSM]–III–R, APA, 1987; DSM–IV, APA, 1994; DSM-V, APA, 2013) which may artificially inflate associations between anger and PTSD. However, studies that have directly investigated this have found correlations do not substantially decrease when items measuring anger and irritability within PTSD scales were removed suggesting that the correlation between PTSD and anger is not a methodological artefact (Novaco & Chemtob, 2002; Orth, Cahill, Foa & Maercker, 2008). Thus anger can feature in PTSD and arguably exacerbate PTSD in its own right. E.g., loss of independence following TBI may lead to frustration and anger, thus heightening emotional arousal which may impact on relationships with others, feeling isolated and further exacerbating PTSD.

Alcohol misuse is more prevalent in the US (Bray et al., 2006) and UK military compared to civilian populations (Fear et al., 2007). It is reported as the most frequent post-deployment mental health problem (prevalence rates up to 13%; Fear et al., 2010) and is particularly associated with combat engagement (Hotopf et al., 2006; Jones & Fear, 2010). Increased risk of alcohol misuse has been associated with PTSD co-morbidity (Carter, Capone & Short, 2011), PTSD severity (McDevitt–Murphy et al., 2010), presence of mTBI (Rona et al., 2012; Hoge et al., 2004), and highly positively correlated with anger problems (Sayer et al., 2010). It is plausible alcohol use may serve as self-medication to deal with traumatic experiences, i.e., a maladaptive emotional regulation strategy. However, the numbing effect of alcohol may prevent the processing of traumatic memories that may in turn exacerbate PTSD.

The specific function that maladaptive emotional regulation strategies (MERS: anger and alcohol use) play in relation to TBI and PTSD in military veterans requires further understanding. Whilst the above studies show direct associations between anger and alcohol use in response to TBI and/or PTSD, no study to date has investigated their indirect role, i.e., whether anger and alcohol use mediates the effect that TBI has on PTSD. For example, TBI may disrupt connectivity between the frontal and limbic brain structures and thus impair ability to inhibit and regulate emotional responses such as anger. Increased levels of arousal via anger may interfere with the processing of traumatic memories as well as lead to ineffective problem solving and decreased social support, in turn facilitating distress and hyperarousal thus increasing overall PTSD symptoms. Alternatively, in order to cope with the effects of TBI, alcohol may be used as a form of self-medication. The numbing effects of alcohol use may prevent successful trauma processing which may contribute to chronic PTSD.

Additionally, in light of the emerging evidence that veterans who have suffered a blast related TBI (relative to a non-blast related TBI) report elevated levels of psychological symptoms due to impaired regulation of emotions, blast related TBIs may be associated with increased levels of anger, greater alcohol use and more severe PTSD symptoms than blunt mechanisms of injury.

Aims

The first aim will further explore data from Murphy et al. (2015) to investigate if MERS mediate the effect that TBI severity has on PTSD severity. The second aim will test whether blast related TBIs are associated with increased levels of anger, greater alcohol use and more severe PTSD symptoms than blunt mechanisms of injury or no injury. The third aim will explore if MERS influence the association between TBI severity and PTSD recovery at 16 month follow-up.

Specific Hypotheses

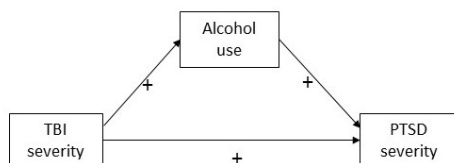
Hypothesis 1.

The effect of the severity of TBI on PTSD severity will be mediated via scores for alcohol use on the AUDIT (Figure 1, model 1).

Hypothesis 2.

The effect of the severity of TBI on PTSD severity will be mediated via scores for anger on the DAR-5 (Figure 1, model 2).

Model 1) Alcohol use as a single mediator



Model 2) Anger as a single mediator

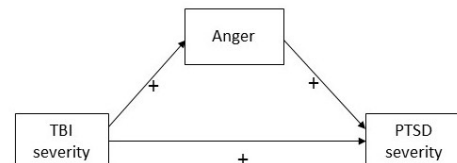


Figure 1. Single mediator models: Alcohol use (model 1) and anger (model 2) will mediate the effect of TBI severity on PTSD severity.

Hypothesis 3.

Blast related TBIs will be more strongly associated with increased levels of anger, greater alcohol use and more severe PTSD symptoms than blunt mechanisms of injury or no injury.

Hypothesis 4.

The association between TBI severity and PTSD recovery at 16 month follow-up will be associated with scores for alcohol use on the AUDIT, in that increased AUDIT scores will decrease PTSD recovery.

Hypothesis 5.

The association between TBI severity and PTSD recovery at 16 month follow-up will be associated with scores for anger on the DAR-5, in that increased DAR-5 scores will decrease PTSD recovery.

Method

Setting

The charity Combat Stress has been commissioned by the UK Department of Health as a national specialist service to treat UK veterans with PTSD (Combat Stress, 2013).

Participants

Participants were 123 UK military veterans (Time 1 sample) originally recruited to investigate prevalence of TBI in those accessing Combat Stress (Murphy et al. 2015). The Murphy et al. inclusion criteria were a) new admissions to Combat Stress from south England between January and July 2014, b) experiencing mental health difficulties and c) veterans had requested further support. Exclusion criteria were veterans who were not experiencing mental health difficulties and/or did not require further support. The majority of participants had served in the Army (77.2%), were male (121 males vs. 2 females) and mean age 47.2 years (sd= 12.5). Table 1 shows mental health characteristics.

Table 1. Mental health characteristics of Time 1 sample (n=123)

Mental health outcome (measures used)	Mean (sd)
Depression (Patient Health Questionnaire-9)	15.45 (6.33)
Anxiety (Generalised Anxiety Dirsoder-7)	12.59 (5.96)
Anger (Dimensions of Anger Reactions-5)	15.24 (5.29)

PTSD (Impact of Events Scale-Revised)	46.06 (22.98)
Alcohol use (Alcohol Use Disorders Identification Test)	9.72 (8.73)

For the current study, inclusion criteria were having participated in the Murphy et al. (2015) study. Exclusion criteria was presence of TBI acquired through physical illness, e.g., a brain tumour.

Design

Cross-sectional survey design was used for secondary data analyses of the Time 1 sample (Murphy et al., 2015). Longitudinal follow-up at 16 months (Time 2) was conducted to obtain cause of injury and PTSD symptom data. Indirect effects on the relationship between TBI severity and PTSD severity were explored using TBI severity as the predictor, PTSD severity at Time 1 and 2 as the outcome, alcohol use and anger (MERS) as mediators, and cause of injury as a moderator.

Measures

Brain Injury Screening Index (BISI).

The BISI (Disabilities Trust Foundation) consists of six items screening for head injuries and associated conditions. This tool has been shown to be valid (Pitman, Haddelsey, Ramos, Oddy, & Fortescue, 2014) and reliable (O'Sullivan, 2015) in screening for TBI. Presence of TBI was determined if participants reported experiencing a serious blow to the head and one or more of the following immediate symptoms: 1) AMS (feeling dizzy, unsteady or dazed); 2) memory loss over one hour; or (3) LOC.

TBI severity was classified through length of LOC in a 6-point Likert scale 0 to 5 using the following ordinal scale: no history = none (0); AMS but no LOC = minor concussion (1); LOC ≤ 10 minutes = mTBI (2); LOC ≥ 11 to ≤ 30 minutes = complicated mTBI (3); LOC ≥ 31 to ≤ 24 hours = moderate TBI (4); LOC ≥ 24 hours = severe TBI (5). The three levels of mild injury (minor concussion, mTBI and complicated mTBI) have been used in previous research investigating TBI (Davies, Williams, Hinder, Burgess & Mounce, 2012, page E22) and have been shown to differentiate outcomes of mTBI (Davis et al., 2012). Furthermore, using mTBI subcategories allowed greater sensitivity to a wider range of mild injuries

which was in line with recommendations by the European Federation of Neurological Society (Vos et al., 2002).

Impact of Events Scale (IES-R).

The IES-R (Weiss & Marmar, 1997) assessed PTSD based on DSM-IV criteria: Intrusion, Avoidance and Hyperarousal (APA, 2000). The measure consists of 22 items scored on a 5-point Likert scale 0 to 4, higher scores indicating greater symptomatology. Internal consistency has been shown to be good with Cronbach's alpha ranging from .78 to .86 for total and subscale scores (Horowitz, Wilner & Alvarez, 1979).

Alcohol Use Disorders Identification Test (AUDIT).

The AUDIT (Babor, Higgins-Biddle, Saunders & Monteiro, 2001) assessed alcohol use and consists of ten items scored on a 5-point Likert scale 0 to 4, higher scores indicating greater symptomatology. Internal consistency has been shown to be good, Cronbach's alpha of .76 (Ivis, Adlaf & Rehm, 2000).

Dimensions of Anger Reactions (DAR-5).

The DAR-5 (Forbes et al., 2014a) assessed anger problems and consists of 5 items scored on a 5-point Likert scale 1 to 5, higher scores indicating greater symptomatology. Internal consistency has been shown to be good with Cronbach's alpha ranging from .88 to .90 (Forbes et al., 2014b; Hawthorne et al., 2006).

Brief Traumatic Brain Injury Screen (BTBIS).

The BTBIS (Schwab, Baker, Ivins, Sluss-Tiller, Lux & Warden, 2006; Schwab et al., 2007) consisted of three items that screen for TBI in veterans. Preliminary psychometrics indicated high positive predictive value (83.7%) in detecting mTBI in US military personnel. For this study, only item 1: "Did you have any injury(ies) during your deployment from any of the following? Fragment, bullet, vehicular accident, fall, blast and other-specify" was used to determine cause of injury in those who had endorsed TBI at Time 1.

Procedure

Murphy et al. (2015) administered the IES-R, AUDIT, DAR-5 and BISI (Time 1) and provided access to these data for secondary data analyses. All Time 1 participants were sent a cover letter, information sheet and consent form for follow-up data collection (Appendices A1-3). Consenters were contacted via telephone by the author between September 2015 – January 2016 (Time 2) to administer the IES-R and BTBIS. A telephone script was used to ensure interview consistency (Appendix A.4).

The minimum required sample size for mediation analyses was 71, based on medium effect sizes for path *a* and *b*, power = .80 and alpha = .05 (Fritz & MacKinnon, 2007; Table 3, p. 237)⁵.

Data analysis

In preparation for secondary data analyses, the IES-R, AUDIT, DAR-5, and BISI were inspected for scores outside of scale ranges. For the IES-R, sub-scale scores were summed to ensure these matched the total IES-R score. Twenty participants were identified as having potential data errors. These were reported back to Murphy et al. (2015) who were able to provide corrected data.

Parametric assumptions of normality and homogeneity of variance were checked using histograms and Kolmogorov-Smirnov and Levene's tests respectively. Outliers were checked using boxplots; none were identified. Alpha level was set at $p = .05$ (two-tailed). For correlations, preliminary analyses were performed to ensure adherence to assumptions of normality, linearity and homoscedasticity. Likewise, preliminary analyses tested multiple regression assumptions of outliers, normality, linearity, homoscedasticity, independence of residuals, multicollinearity and singularity (Pallant, 2007, p. 148-9); none were violated.

For the hypotheses that the effect of the severity of TBI on PTSD severity will be mediated via a) scores for alcohol use on the AUDIT (hypothesis 1) or b) scores for anger on the DAR-5 (hypothesis 2), mediation analyses were conducted for the cross-sectional sample ($n = 108$). Mediation analyses were

⁵ Appendix C.1 provides further details on sample size calculation.

conducted in IBM SPSS v22 PROCESS v2.15 macros using an ordinary least square multiple regression with 10,000 bootstrap samples procedure (Hayes, 2013). In order to determine whether there was evidence of a mediation effect, bias-corrected 95% confidence intervals were obtained for the indirect effect (ab), i.e., if the confidence interval crossed zero this would be taken as evidence of no mediation effect (Hayes, 2013). This method was chosen over the Baron and Kenny (1986) causal steps method for the following reasons: a) A requirement of the Baron and Kenny method is to calculate the product of a and b paths then divide by the standard error of the cross product to yield a z statistic which is assessed for significance using normal probability distribution. However, MacKinnon et al. (1998) reported tests for the mediated effect based on normal distribution theory can yield inaccurate confidence limits and the product of two normally distributed variables is not itself normally distributed but often asymmetric and highly kurtotic. Alternative tests based on the asymmetric distribution of the product of two normally distributed variables have been shown to outperform traditional methods (MacKinnon et al. 2002; MacKinnon et al. 2004). b) The Baron and Kenny method requires rejection of three null hypotheses in order to determine a mediation effect; failure at any one step leads to concluding there was no mediation. However, requiring three steps increases proneness of failing to reject a false null hypothesis or incorrectly rejecting a true one thus it is one of the least powerful approaches to testing mediation. Rather, it is more advantageous to conduct a single inference test of the indirect effect (ab). See Hayes (2013, p. 166 to 172) for further details.

For the hypothesis that blast related TBIs will be more strongly associated with increased levels of anger, greater alcohol use and more severe PTSD symptoms than blunt mechanisms of injury or no injury (hypothesis 3), correlations were conducted between the IES-R, DAR-5 and AUDIT within each cause of injury subgroup (no injury, blunt injury, blast injury, total $n=29$). Spearman's rho (r) was used due to non-normality of the self-report data. Significance testing of the correlation coefficients between the IES-R, DAR-5 and AUDIT within each cause of injury category were not conducted due to violation of the assumption of not having a minimum of 20 cases per group (Pallant, 2007, p. 138), thus the exploratory correlational analyses were descriptive only.

For the hypotheses that the effect of the severity of TBI on PTSD recovery at 16 month follow-up will be associated with a) scores for alcohol use on the AUDIT (hypothesis 4) or b) scores for anger on the DAR-5 (hypothesis 5), a PTSD recovery outcome variable was calculated by regressing Time 2 IES-R on Time 1 IES-R and saving the residuals, i.e., the residualised change score which reflected symptom change whilst controlling for Time 1 symptoms (Tucker, Damarin & Messick, 1966). Residuals were reversed so that negative scores reflected worsened outcome whilst positive scores reflected improvement. Partial correlation was carried out between TBI severity and the IES-R residualised change score whilst controlling for either AUDIT ($n=28$) or DAR-5 ($n=29$).

Effect sizes were interpreted as follows: r and phi coefficient: small .1, medium .3 and large .5; partial eta squared (η^2_p): small .01, medium .06 and large .14; Cohen's d : small .2, medium .5 and large .8 (Cohen, 1988). For the single mediation models, partially standardised effect sizes⁶ were reported (Hayes, 2013, p.184-93).

Results

Thirty eight participants (30.9%) from Time 1 ($n=123$) consented to follow-up, of which $n=33$ (26.8%) provided data (Time 2 sample)⁷. Preliminary analyses of the Time 1 sample showed $n=6$ veterans acquired TBI through physical illness. In addition, only one participant was classified as having a severe TBI (LOC= 3 days), thus these individuals were excluded. The included Time 1 sample was $n=116$, with a mean age of 46.91 years ($sd=12.66$), the majority were male (ratio 114 males to 2 females) and had served in the Army ($n=90$, 77.6%). Seventy seven participants (66.4%) reported a history of TBI, the majority occurring during military service ($n=52$, 69.3%). Participants scoring above the questionnaire cut-offs were as follows: $n=88$ (74.5%) for PTSD (IES-R total >33); $n=62$ (56.4%) for hazardous drinking (AUDIT total >8); and $n=90$ (69.9%) for anger problems (DAR-5 total >12). After applying exclusion criteria to the Time 2 sample, $n=29$ remained. Twenty four participants (82.8%) had a history of TBI, of which the

⁶ This represents an effect relative to the standard deviation of the outcome rather than its original scale, thereby giving the effect context relative to the variability in the outcome.

⁷ Appendix C2.1 shows differences in demographic and clinical characteristics of Time 2 responders vs. non-responders

majority occurred during military service (n= 16, 95.8%); n=7 (17.9%) for hazardous drinking; and n=21 (65.5%) for anger problems. Table 2 shows severity, occurrence and nature (Time 2 participants only) of TBI and mean scores for mental health outcomes at Time 1 and 2⁸.

Table 2. TBI severity rates, nature of TBI (Time 2 participants only) and mean scores for mental health outcomes at Times 1 and 2.

	Time 1 (n=116) N (%) / Mean (sd) / Median ^a (25 th - 75 th percentile)	Time 2 (n=29) N (%) / Mean (sd) / Median ^a (25 th - 75 th percentile)
TBI severity		
LOC	2 min 30 sec (1 min 15 sec – 27 min 30 sec) ^a	2 min (37.8 sec – 95 min) ^a
Occurrence of TBI in military service		
Before	17 (22.7)	7 (29.2)
During	52 (69.3)	16 (95.8)
After	6 (8)	1 (4.2)
BTBIS: Cause of TBI (Time 2 sample only)		
No head injury	-	5 (17.2)
Fragment	-	0 (0)
Bullet	-	0 (0)
Vehicular	-	4 (13.8)
Fall	-	3 (10.3)
Blast	-	6 (20.7)
Other- Assaulted	-	6 (20.7)
Other- Hit by rocks	-	2 (6.9)
Other- Sports concussion	-	3 (10.3)
Mental health outcomes		
IES-R	46.68 (23.16)	46.29 (23.73)
DAR-5	15.32 (5.32)	16.38 (5.75)
AUDIT	10.06 (8.87)	8.07 (8.12)

Notes: sd= standard deviation; LOC= Loss of consciousness

Cause of injury (Time 2 participants)

Table 2 shows n=5 participants reported no history of TBI at Time 1. Of those reporting a TBI, blunt injuries (fall, vehicular or other, n=18) outnumbered

⁸ Appendix C3.1 shows frequency rates of TBI severity at Time 1 and 2.

blast injuries ($n = 6$). No TBIs were due to either fragment or bullet. For the purpose of analyses, injury mechanisms were coded as nominal categories as follows: 0= no injury, 1= blunt force injury and 2= blast force injury.

Correlations between predictor and outcome variables

Table 3 shows PTSD severity was significantly positively associated with the predictor variables of TBI severity and anger (small to medium effect sizes). However, PTSD severity was not significantly associated with alcohol use. Inter-correlations between predictor variables revealed no other significant correlations.

Table 3. Correlations between TBI severity, IES-R total, DAR-5 and AUDIT.

	TBI severity	DAR-5	AUDIT
IES-R total	.209* (110)	.400** (108)	.074 (108)
TBI severity	-	.202* (113)	.051 (110)
DAR-5	-	-	.048 (109)

Notes- Spearman's rho (r) used due to non-normality of data.

* $p < .05$; ** $p < .01$.

Number in brackets denotes n .

Hypothesis 1: The effect of the severity of TBI on PTSD severity will be mediated via scores for alcohol use on the AUDIT

Model 1 (Figure 2 and Appendix C4.1) shows there was a significant direct effect of TBI severity on PTSD severity ($c' = 4.023$) when alcohol use was held constant, i.e., for every one unit increase in TBI severity, IES-R increased by 4 points in those with zero alcohol use. Inspection of the indirect pathway via alcohol use revealed TBI severity did not significantly predict alcohol use ($a = -0.106$), nor did alcohol use significantly predict PTSD severity ($b = 0.470$). A bias-corrected bootstrap 95% confidence interval for the indirect effect ($ab = -0.050$) crossed zero (-1.012 to 0.514). The partial standardised effect size was 0.002 (i.e. small). Thus there was no evidence that alcohol use mediated the effect that TBI severity had on PTSD severity.

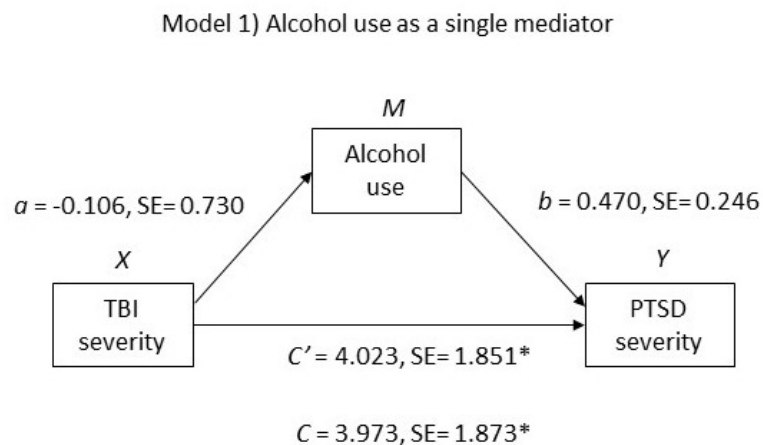


Figure 2. Model 1 shows unstandardised coefficients for alcohol use mediating the effect of TBI severity on PTSD severity. X = predictor: TBI severity; M = mediator: alcohol use; Y = outcome: PTSD severity. * $p < .05$; ** $p < .01$; *** $p < .001$. $n = 108$.

Hypothesis 2: The effect of the severity of TBI on PTSD severity will be mediated via scores for anger on the DAR-5

Model 2 (Figure 3 and Appendix C4.2) shows there was a non-significant direct effect of TBI severity on PTSD severity ($c' = 3.168$) when anger was held constant. Inspection of the indirect pathway via anger shows TBI severity did not significantly predict anger ($a = 0.815$). However, anger significantly predicted PTSD severity ($b = 1.423$) in that when TBI severity was held constant, a one unit increase in anger increased IES-R by 1.423 points. A bias-corrected bootstrap 95% confidence interval for the indirect effect ($ab = 1.159$) was above zero (0.014 to 3.106) which suggested evidence that increased anger mediated the effect that TBI severity had on PTSD severity. The partial standardised effect size was 0.051 (small).

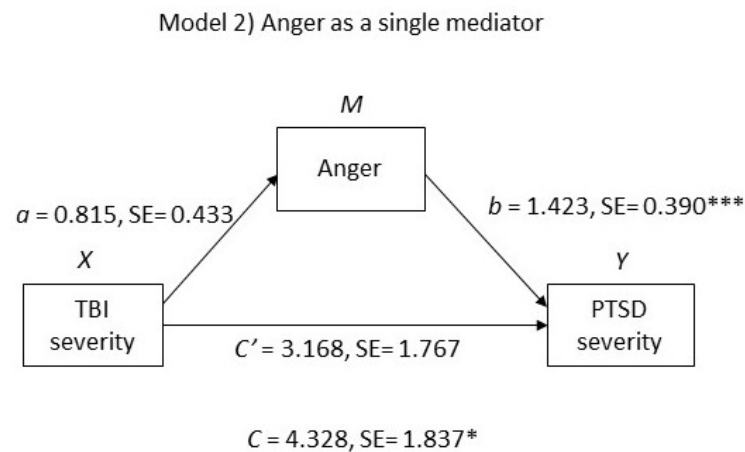


Figure 3. Model 2 shows unstandardised coefficients for anger mediating the effect of TBI severity on PTSD severity. X= predictor: TBI severity; M= mediator: anger; Y= outcome: PTSD severity. * $p < .05$; ** $p < .01$; *** $p < .001$. $n = 108$.

Hypothesis 3: Blast related TBIs will be more strongly associated with increased levels of anger, greater alcohol use and more severe PTSD symptoms than blunt mechanisms of injury or no injury.

Table 4 shows that for those with no TBI, PTSD severity was significantly positively correlated with anger reactions (large effect size), but not significantly associated with alcohol use. Anger reactions were significantly positively correlated with alcohol use (large effect size). For veterans who reported the cause of injury was due to blunt force, PTSD severity was significantly positively correlated with anger reactions (large effect size). However, alcohol use was not significantly correlated with either PTSD severity or anger. For veterans with a blast TBI, no significant inter-correlations emerged between PTSD severity, anger or alcohol use. Based on descriptive data only (as significance testing of the correlation coefficients between the measures within each cause of injury category were not conducted), there was no evidence that blast related injury was more strongly associated with increased levels of anger, greater alcohol use or more severe PTSD symptoms than blunt mechanisms of injury or no injury.

Table 4: Correlations between the IES-R total, DAR-5 and AUDIT split by cause of injury categories: no injury, blunt force and blast force.

		DAR- 5	AUDIT
None (n=5)	IES-R	.900*	.800
	DAR-5	-	.900*
Blunt (n=18)	IES-R	.701**	-.276
	DAR-5	-	-.159
Blast (n=6)	IES-R	.800	-.667
	DAR-5	-	-.564

Notes- Spearman's rho (r) used due to non-normality of data. * $p < .05$; ** $p < .01$.

Hypothesis 4: The association between TBI severity and PTSD recovery at 16 month follow-up will be associated with scores for alcohol use on the AUDIT, in that increased AUDIT scores will decrease PTSD recovery.

Table 5 shows the zero-order correlation between TBI severity and PTSD recovery at 16 months (i.e., the residualised IES-R change score between Time 1 and Time 2) was non-significant suggesting the severity of TBI was not associated with the degree of PTSD recovery. There was no significant correlation between TBI severity and PTSD recovery at 16 months when alcohol use was controlled for, thus there was no evidence that the association between TBI severity and PTSD recovery was influenced by alcohol use.

Table 5: Partial correlation to explore the relationship between TBI severity and PTSD recovery at 16 months controlling for alcohol use

	Zero order correlations		Partial correlation
	TBI severity	IES-R residualised T1-T2 change	IES-R residualised T1-T2 change controlling for AUDIT
TBI severity	-	-.143	-.131
AUDIT	-.184	.182	-

Notes- Spearman's rho (r) used due to non-normality of data. * $p < .05$; ** $p < .01$. $n = 28$

Hypothesis 5: The association between TBI severity on PTSD recovery at 16 month follow-up will be associated with scores for anger on the DAR-5, in that increased DAR-5 scores will decrease PTSD recovery.

Table 6 shows the zero-order correlation between TBI severity and PTSD recovery at 16 months was non-significant suggesting the severity of TBI was not associated with the degree of PTSD recovery. There was no significant correlation between TBI severity and PTSD recovery at 16 months when anger was controlled for, thus there was no evidence that the association between TBI severity and PTSD recovery was influenced by anger.

Table 6: Partial correlation to explore the relationship between TBI severity and PTSD recovery at 16 months controlling for anger

	Zero order correlations		Partial correlation
	TBI severity	IES-R residualised T1-T2 change	IES-R residualised T1-T2 change controlling for DAR-5
TBI severity	-	-.143	-.141
DAR-5	.031	-.124	-

Notes- Spearman's rho (r) used due to non-normality of data. * $p < .05$; ** $p < .01$. $n = 29$

Discussion

Based on a UK military veteran sample, this study investigated a) whether maladaptive emotional regulation strategies (MERS: alcohol use and anger) mediated the effect that TBI severity had on PTSD severity, b) whether blast related TBIs were associated with increased levels of anger, greater alcohol use and more severe PTSD symptoms than blunt mechanisms of injury or no injury, and c) if increased alcohol use or anger influenced the association between TBI severity and PTSD recovery, controlling for Time 1 PTSD symptoms.

There was partial support for maladaptive emotional regulation strategies, specifically anger, mediating the effect that TBI severity had on PTSD severity. Thus the null hypothesis that anger would not mediate the effect of TBI severity on PTSD severity was rejected. In other words, TBI severity was positively associated with PTSD scores and this effect operated due to increased TBI severity leading to higher rates of expressed anger which in turn exacerbated PTSD symptoms. Whilst statistically significant, the clinical significance is

questionable given the small effect size, i.e., the increase in PTSD symptoms via anger was 1.4 points which equates to $\frac{1}{20}$ of an IES-R standard deviation. Findings from the total effects suggest that when alcohol use and anger were held constant, i.e. at zero, the positive association between TBI severity and PTSD severity remained with each model significantly demonstrating a similar increase in PTSD symptoms, i.e., 4 points on the IES-R.

There was no support for the hypothesis that blast related TBIs were associated with increased levels of anger, greater alcohol use and more severe PTSD symptoms than blunt mechanisms of injury or no injury. Similarly, there was no support for the hypotheses that increased alcohol use or anger influenced the association between TBI severity and PTSD recovery.

TBI and PTSD

The findings of this study offer partial support to the literature on the association between TBI and PTSD. The view that PTSD could not occur after a TBI associated with impaired or LOC (Sbordone & Liter, 1995) has been challenged as several studies suggest co-occurrence of TBI and PTSD (Bryant, 2001, 2011; Bryant & Harvey, 1998; Harvey & Bryant, 2000; Harvey, Brewin, Jones & Kopelman, 2003; King, 2008). Within this study, TBI severity was positively significantly correlated with PTSD symptoms, although the effect size was small. After controlling for alcohol use and anger, models 1 and 2 showed for every one unit increase in TBI severity, total IES-R scores significantly increased by approximately 4 points. Thus compared to an individual with no history of TBI, those with minor concussion were approximately 4 points higher, mTBI were 8 points higher, complicated mTBI 12 points and moderate TBI 16 points higher. There was also evidence that co-occurrence of TBI and PTSD can operate via anger. However, these findings require cautious interpretation. As shown in Table 2, there is a possibility the cause of head injury was unrelated to the onset of PTSD, e.g., 10% of the Time 2 sample reported the cause of head injury was due to sports concussion and 30% of the Time 1 sample reported the head injury occurred prior to or after military service. This study suggests that increased TBI severity can increase risk of PTSD, which differs from saying that TBI *leads* to PTSD.

The rates of TBI in this study were much higher than those reported in other studies of UK military populations. Rona et al. (2012) highlight how rates can differ depending on whether they represent *prevalence* or *incidence* over a specific time period. Murphy et al. (2015) propose the Time 1 sample can be interpreted as representing lifetime incidence rates which would be consistent with other studies reporting TBI life time rates, e.g., 59% in active serving US personnel (Yurgil et al., 2014).

Cause of head injury

The small Time 2 sample prevented significance testing of the psychological symptom correlation coefficients between the cause of injury subgroups thus it cannot be determined whether a particular cause of injury was significantly associated with a greater degree of increased alcohol use, anger or PTSD severity in UK veterans. Thus the findings of this study are not able to either support or counter studies that report blast related TBI (compared to non-blast related TBI) were associated with elevated reporting of anger (Mendez et al., 2013) and PTSD symptoms (Levin et al., 2010) or studies that have concluded there were similar symptomatic outcomes regardless of injury mechanism (Luethcke et al., 2011, Belanger et al., 2009, Belanger et al., 2011, Wilk et al., 2010).

Anger and alcohol use

Anger showed the highest degree of significant inter-correlations with other variables in this study, being positively associated with PTSD symptoms (medium effect size) and TBI severity (small effect size). Whilst the association between anger and PTSD may be unsurprising given that a) anger and irritability are a required diagnostic feature of PTSD and b) the IES-R contained an item specifically assessing irritability and anger, there is evidence to suggest the association between PTSD and anger is not simply a methodological artefact (Novaco & Chemtob, 2002; Orth, Cahill, Foa & Maercker, 2008). Model 2 revealed when TBI was controlled for, anger significantly predicted increased PTSD symptoms in that for every one unit increase in DAR-5, IES-R score increased by 1.4 points which accounted for 15.7% of variance in PTSD symptoms. This is in line with theoretical models that account for the relationship between anger and PTSD. The survival mode theory (Chemtob, Novaco,

Hamada, Gross & Smith, 1997; Novaco & Chemtob, 1998) proposes that individuals with PTSD have a substantially lowered threat perception threshold and that threat perception activates a biologically predisposed survival mode that includes fear and flight reactions as well as anger and fight reactions. An alternative fear avoidance theory (Feeny, Zoellner & Foa, 2000; Foa, Riggs, Masie & Yarczower, 1995; Riggs et al., 1992) hypothesizes that in order to avoid trauma-related feelings of fear that are activated by posttraumatic intrusions, trauma related anger becomes the primary response due to its more positive emotional valence than fear.

Increased anger following TBI may be explained by damage or disruption to connections between frontal and limbic brain structures resulting in a decreased ability to inhibit and regulate emotional responses (Starkstein & Robinson, 1991). TBI may exacerbate negative pre-morbid personality traits (Tate, 2003), i.e., those who were aggressive prior to injury are likely to be more so after injury. Alternatively, anger and aggression may be the product of poor insight and awareness, i.e., anosognosia. Understanding of how anger emerges and influences PTSD has treatment implications, such as pharmacological intervention for anger driven by organic factors or psychotherapy to recognise cognitive schemas and internal experiences and their impact on behaviour (Alderman, 2003). The high proportion of those scoring above the cut-off for anger problems (69.9%) and the finding that anger acted as an underlying mechanism between TBI and PTSD are in line with meta-analytic studies that report a positive association between anger and PTSD severity in military populations (Orth & Wieland, 2006; Taft et al., 2011).

Given the high rate of hazardous drinking found in this study (56.4%), the findings of small and non-significant correlations of alcohol use with PTSD, TBI and anger were surprising. However, given evidence that heavy drinking is part of military culture (Jones & Fear, 2010), it may be difficult to distinguish premorbid “culturally normal” heavy drinking vs. that which is over and above such levels and used as a maladaptive coping mechanism.

Future directions

Future research is warranted on the effects of blast injury in UK veterans. Analyses of indirect effects could be applied to UK cohort data reported by Rona

et al. (2012) and Jones et al. (2014) who currently only report descriptive data on cause of injury. For example, models could test the moderating role of cause of injury on the relationship between TBI and PTSD. Rona et al. also reported data on alcohol use which could be included as a mediator or outcome variable. In addition, alcohol use is reported as the leading mental health difficulty in UK veterans with prevalence rates greater than PTSD (Fear et al., 2010). Further research is required to gain an understanding of the role alcohol use plays across a range of outcomes other than mental health such as social exclusion and physical health, in those currently serving and ex-service members as well as its role in transitioning from military to civilian life (Fear, Wood & Wessely, 2009b).

Limitations

A limitation of this study was the unequal representation of veterans with TBI severities in both the Time 1 and Time 2 samples in that the majority of veterans reported having mTBI which may have influenced findings.

A challenge in understanding the relationship between PTSD and TBI is the overlap in symptoms. TBI status was assessed using the BISI which required endorsing a memory gap. Evidence suggests amnesia is also common to PTSD (Gronwall & Wrightson, 1981) and may contribute to the misdiagnosis of PTSD following TBI (Sumpter & McMillan, 2005). Use of duration of LOC to inform TBI severity may be problematic due to recall bias. Furthermore, classification in this study determined LOC under 10 minutes as mTBI and LOC between 11 and 30 minutes as complicated mTBI. Whilst this classification has been used in other studies investigating TBI, e.g., Davis et al., 2012, there are classification systems that would categorise these as minor and mild (e.g., WHO, 2001). Overlap also occurs when considering anger and PTSD since anger is a diagnostic feature of PTSD. Arguably, the DAR-5 anger measure goes beyond the anger item in the IES-R in that the DAR-5 captures both expression of anger towards other people or situations as well as how an individual may control their anger. However, the overlap in anger as a diagnostic feature may still act as a potential confound.

Statistical power was an issue in this study. Whilst the required sample size calculations used medium effect sizes based on previous literature (Appendix C.1), the obtained effect sizes were small (partially standardised effect sizes ranged 0.002 to 0.051). Fritz and Mackinnon (2007) reported a sample

$n=462$ would be required to detect small effect sizes at power .80, thus Time 1 and 2 samples were underpowered. Furthermore, Time 2 response rate was below anticipated resulting in underpowered analyses exploring cause of injury and PTSD recovery. Murphy et al. (2015) had shown a 67% response rate resulting in a dataset of 123 veterans, thus it was anticipated that approximately 82 individuals would respond to Time 2 follow-up. Relatedly, missing data were minimal in the Time 1 sample (IES-R Total $n=6$ (5.2%); AUDIT $n=6$ (5.2%); DAR-5 $n=3$ (2.6%)), thus imputing these to maximise power would have had minimal effect.

A further issue was the determination of causality in this study. The use of mediation implies a directional relationship, even if only in a statistical sense. Thus the mediation hypotheses require careful interpretation. For example, individuals in this study may have had a high level of premorbid anger prior to developing PTSD or experiencing a head injury. The cross-sectional survey design did not allow determination of cause and effect as no experimental manipulation was done. Whilst the longitudinal approach for PTSD scores at follow-up allow us to conclude these symptoms occurred after the TBI event, it cannot be determined that PTSD may have been present before a head injury occurred. The approach taken in this study was to determine whether data were *consistent with a proposed causal process* that was informed by theory and the literature rather than *asserting causal claims*.

Strengths

This study had access to a hard to reach clinical population that were recruited from a wide geographical UK region and attempted to answer gaps in the literature. To the author's knowledge, no study to date has investigated the role that cause of injury has on PTSD in UK military veterans. The statistical approach used in this study allowed the answering of *whether* or *if* TBI severity was associated with PTSD severity as well as *how* (via MERS) and *when* that relationship was present (in the context of certain injuries).

Conclusion

This study explored the association between TBI severity, PTSD severity, the mediating effect of alcohol use and anger and the effect of injury mechanisms

on self-reported symptoms in UK military veterans. Despite evidence in the literature of associations between TBI, PTSD, alcohol use and anger, and mixed evidence of differential psychological symptoms in response to blast vs. blunt injuries, the indirect effects that link these complaints remains unknown. This study explored these effects using regression based mediation and exploratory correlational analyses in a sample of UK military veterans. Findings revealed support for the role of anger in mediating the relationship that TBI severity had on PTSD symptoms. There was no support that cause of injury was associated with differential psychological symptoms or that alcohol use or anger affected the relationship between TBI severity and PTSD recovery at 16 month follow-up.

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Appendix A: Participant pack

A1) Cover letter.



THE VETERANS'
MENTAL HEALTH CHARITY

Name

Address

Address

Address

Postcode

Tyrwhitt House ■ Oaklawn Road
Leatherhead ■ Surrey ■ KT22 0BX

Tel: 01372 587 000

Fax: 01372 587 101

Helpline: 0800 138 1619

contactus@combatstress.org.uk
www.combatstress.org.uk

18 August 2015

Dear Name,

I am a Trainee Clinical Psychologist based at the University of Exeter. I am working with Combat Stress doing a research study to understand how the cause of a head injury (such as that from a vehicle accident or a bomb blast) may affect post-traumatic stress disorder (PTSD) symptoms in UK military personnel.

As you have previously taken part in research with Combat Stress, I would like to invite you to take part in this follow-up study. The study is completely confidential, it will not impact your treatment at Combat Stress or any other support you have now or in the future.

The study will involve me contacting you via telephone to do a survey which would last about 10 to 15 minutes. **Should you agree to participate in the study, please complete and return the "consent to participate" form to Combat Stress. I will then contact you via telephone.**

If you have any questions about this study, I can be contacted via email on mr388@exeter.ac.uk or telephone 07490 112 842. Please find enclosed an information sheet titled "Nature of head injury and post-traumatic stress disorder (PTSD)".

Thank you in anticipation of your time.

Yours sincerely,

Mark Rose
Trainee Clinical Psychologist
University of Exeter

A2) Information sheet.



Study title: Nature of head injury and post-traumatic stress disorder (PTSD)

Participant Information Sheet

My name is Mark Rose and I am a Trainee Clinical Psychologist based at the University of Exeter. I am doing research to understand how the cause of a head injury (such as that from a vehicle accident or a bomb blast) may affect post-traumatic stress disorder (PTSD) symptoms in UK military personnel.

I would like to invite you to take part in this follow-up study. However, before you make a decision whether or not you would like to take part, please read this information sheet carefully. If you have any questions after reading this, please feel free to contact me directly (contact details are given below). *Thank you for taking the time to read this.*

Summary of the study

This follow-up study aims to investigate how the cause of a head injury might affect PTSD symptoms. Should you agree to participate, you will be involved in answering a short telephone questionnaire survey. This should take between 10 to 15 minutes of your time.

Aim of the study

We know that experiencing a traumatic event may lead to a condition known as PTSD. Whilst we have a good idea about how this can happen, less is known about how PTSD can develop in those who have also suffered a head injury. Understanding more about the nature of how the head injury happened and the person's symptoms of PTSD may help us understand more about how people recover.

Why have I been chosen?

You have been chosen because you previously took part in a study for Combat Stress. We are contacting everyone who participated to seek an opportunity to collect more information.

Do I have to take part?

It is up to you whether or not to take part. If you do decide to take part, please return the enclosed 'consent to participate' sheet to Combat Stress. I will then contact you via telephone to discuss the research with you in more detail and give you the opportunity to ask any questions. The survey can then be completed over the telephone.

If you decide to take part you are still free to end your participation at any time and without giving a reason. A decision to stop at any time, or a decision not to take part, will not affect the standard of care you receive from Combat Stress. Taking part in the study will have no effect on any treatment you currently receive.

What will happen to me if I take part? What do I have to do?

Taking part in this follow-up study involves completing a telephone survey that asks about your treatment for PTSD, if you are currently experiencing any symptoms of PTSD, and if you have had a head injury in the past, some information about the cause of the injury. The survey will

take approximately 10 to 15 minutes to complete. Once you have completed the survey, your responses will be kept in a secure database. All details will remain confidential and secure.

What are the possible disadvantages and risks of taking part?

Being part of this research will involve you giving up your time to complete the survey over the phone with me. Some individuals may find some of the questions difficult or upsetting. If for any reason you find the survey distressing or you have concerns, please contact myself or staff at Combat Stress who will be happy to discuss the matter further.

These help lines and websites may also be helpful:

- Combat Stress. Helpline: 0800 1381 619 (24 hours)
- Post-traumatic stress disorder. www.ptsd.org.uk. For ex-servicemen and women, and anyone who has PTSD.
- Anxiety UK. Helpline: 08444 775 774 (Monday to Friday 9.30am to 5.30pm), www.anxietyuk.org.uk. Provides fact sheets for anxiety disorders (including PTSD).
- ASSIST trauma care. Helpline: 01788 560 800, www.assisttraumacare.org.uk. Support, understanding and therapy for people experiencing PTSD, and families and carers.

What are the possible benefits of taking part?

Whilst there will be no direct or immediate benefit to you taking part in this research, the information we get will hopefully deepen our understanding of the relationship between the cause of head injury and PTSD. This knowledge may inform better support for those with a head injury and PTSD.

What will happen to the results of the study?

I aim to publish the work in an academic journal. Upon request, I will provide you with a summary about the results of the research. Please indicate on the consent sheet if you would like a summary of the results. Your identity will not be revealed in any report or publication. Our research is often reported on the Mood Disorders Centre website at <http://www.centres.ex.ac.uk/mood>

Who has reviewed the study?

All research is looked at by a group of people known as a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by the University of Exeter Psychology Research Ethics Committee.

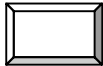

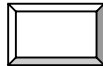

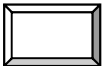
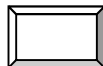
Contact for further information

If you would like any advice about participating in research you can contact the Association for Research Ethics, an organization that offers information and advice on research. The address is Office 13, Cherry Drive, Durham, DH6 2BG. Telephone- 0191 520 9500. Email- info@arec.org.uk, website- <http://www.arec.org.uk/>

If you have any further questions please feel free to contact Mark Rose, the study's Principal Investigator, at mr388@exeter.ac.uk or telephone 07490 112 842.

Thank you for considering taking part in this study.

A3) Consent form.**Consent to Participate Sheet****Study title: Nature of head injury and post-traumatic stress disorder (PTSD)**Please **INITIAL** boxes

- A) I have read and understand the information sheet dated 18-08-2015. 
- B) I consent to be contacted by Mark Rose to take part in the follow-up study. 
- C) I am aware that I can contact Mark Rose (email: mr388@exeter.ac.uk or
telephone 07490 112 842) to discuss any aspect of the study before taking part. 
- D) I am aware my routine care under Combat Stress will not be affected
by taking part in this study. 
- E) I am aware that I have the right to withdraw from the study at any time. 
- F) Please initial if you would like to receive a summary of the results once
the study has finished. 

Name:.....**Contact details:**

Address:

.....

.....

Telephone no:.....

Email:.....

Preferred contact type (telephone or email):

If by telephone, preferred time of day:

Signature:**Date:**

A4) Telephone interview script.

Before phoning, look in Combat Stress database to check if participant answered positive for head injury at Time 2

Participant ID		
Positive for head injury? (tick as appropriate)	Yes=	No=

Hello, my name is Mark Rose. Could I speak to (name of participant) please?

- If participant is speaking, continue below.
- If participant is not speaking, check this is the right number for them.
- If participant not available, determine a better time to call back.
- If wrong number, apologies for taking their time and end call.

I'm working on a study called "The nature of head injury and post-traumatic stress disorder". You recently returned a consent to participate form to Combat Stress. Many thanks for doing this. Is now an OK time to discuss the study?

- If yes, continue below.
- If no but still interested in participating, determine a better time to call back
- If no, thank them for their time and end call.

We have invited you to take part in this study because you recently took part in a study for Combat Stress in 2014 asking information about your mental health and about head injury. We have contacted everyone who participated to seek an opportunity to collect more data.

The purpose of this telephone survey is to ask about your treatment for PTSD, if you have experienced any symptoms of PTSD over the past 7 days, and if you have had a head injury in the past, some information about the cause of the injury. This is a one-off survey and will take approximately 10 to 15 minutes to complete.

Your responses will be kept confidential and anonymous. However, if risky behaviours are disclosed, such as risk of harm to self or others, then I would need to break this confidentiality and speak with Combat Stress about this. Also, your participation in this study is completely voluntary. You are free not to participate or to withdraw at any time, for whatever reason. No matter what decision you make, this will not effect the care you are currently receiving, or in the future, from Combat Stress. Are you happy to continue with the survey?

- If participant is happy to continue with survey, continue below.
- Answer any questions directly related to the research project.
- If participant wishes to discuss matters beyond the research project then direct them back to Combat Stress.
- If no, thank them for their time and end call.

If calling their landline: For reasons of safety, can I confirm that this is your home telephone number and the address is the same as what you provided on the returned consent form, (READ OUT ADDRESS)

- Yes, home telephone number and same address, proceed to questions about treatment for PTSD

- No, different address, ask if you can take details of their current location for reasons of safety.

Location: _____

If calling a mobile number: *For reasons of safety, can I confirm whether you are at your home address that you provided on the returned consent form, (READ OUT ADDRESS)*

- Yes, participant is at their home address, proceed to questions about treatment for PTSD
- No, ask if you can take details of their current location for reasons of safety.

Location: _____

So the first set of questions are about treatment for PTSD. Have you or are you currently receiving treatment for PTSD from Combat Stress or another health care provider? (tick and follow-up as appropriate)

<u>Yes, in the past.</u> <i>Was that with Combat Stress?</i> <i>If not, who was the care provider?</i> <i>If so, for how long?</i>	
<u>Yes, currently in treatment with Combat Stress.</u> <i>If so, for how long?</i>	
<u>Yes, another health care provider.</u> <i>If so, who?</i> <i>For how long?</i>	
<u>No, not received any treatment yet.</u>	

The next set of questions are about PTSD symptoms. Can I confirm, during your military service, did you go through a traumatic experience that led to you seeking support from Combat Stress?

I am going to read out a list of difficulties people sometimes have after stressful life events. There are around 20 in total. After hearing each item, please tell me how distressing each difficulty has been for you DURING THE PAST SEVEN DAYS.

Each difficulty is rated as follows- Not at all, A little bit, Moderately, Quite a bit and Extremely.

It may be helpful to write down those five ratings or I can repeat them back at any time.

- Provide time for them to write down ratings

How much were you distressed or bothered by these difficulties in the past 7 days ?

	0 Not at all	1 A little bit	2 Moderately	3 Quite a bit	4 Extremely
1. Any reminder brought back feelings about it.					
2. I had trouble staying asleep.					
3. Other things kept making me think about it.					
4. I felt irritable and angry.					
5. I avoided letting myself get upset when I thought about it or was reminded of it.					
6. I thought about it when I didn't mean to.					
7. I felt as if it hadn't happened or wasn't real..					
8. I stayed away from reminders of it.					
9. Pictures about it popped into my mind.					
10. I was jumpy and easily startled.					
11. I tried not to think about it.					
12. I was aware that I still had a lot of feelings about it, but I didn't deal with them.					
13. My feelings about it were kind of numb.					
14. I found myself acting or feeling like I was back at that time.					
15. I had trouble falling asleep.					
16. I had waves of strong feelings about it.					
17. I tried to remove it from my memory.					
18. I had trouble concentrating.					
19. Reminders of it caused me to have physical reactions, such as sweating, trouble breathing, nausea, or a pounding heart.					
20. I had dreams about it.					

21. I felt watchful and on-guard.					
22. I tried not to talk about it.					

If negative for head injury:

OK, thank you for rating those difficulties. That is the end of the survey. That has been really helpful and thank you for giving up your time.

- End call

If positive for head injury:

The next question is about head injury.

When Combat Stress spoke with you between October and December 2014, you reported that you had received a head injury.

Is the head injury related to the traumatic event that you are seeing Combat Stress for?

Tick as appropriate	Yes=	No=
---------------------	------	-----

Were the head injury(ies) during your deployment from any of the following? (Tick all that apply):

Fragment
Bullet
Vehicular (any type of vehicle, including aircraft)
Fall
Blast (Improvised Explosive Device, RPG, Land mine, Grenade, etc.)
Other- please specify

OK, thank you for answering these questions. That is the end of the survey. That has been really helpful and thank you for giving up your time.

- End call

Appendix B: Ethics documentation

B1) School ethics.

Your application for ethical approval (2015/958) has been cond... - Rose, Mark

Page 1 of 1

Your application for ethical approval (2015/958) has been conditionally accepted

apache@exeter.ac.uk on behalf of Ethics Approval System <D.M.Salway@exeter.ac.uk>

Tue 04/08/2015 19:18

To: Rose, Mark <mr388@exeter.ac.uk>;

Ethical Approval system

Your application (2015/958) entitled Mediating and moderating effects of maladaptive emotion regulation, injury type and post-concussion symptoms in the relationship between TBI and PTSD in UK military personnel has been conditionally accepted

Please visit <http://www.exeter.ac.uk/staff/ethicalapproval/>

Please click on the link above and select the relevant application from the list. The conditions are as follows:

As agreed via email, regarding ascertaining the participant's location, this is to be incorporated into the telephone script. After the researcher has described the study to the participant and asked if they are happy to continue with the telephone survey, the following dialogue will now be inserted to the script: "If I have phoned them on their landline, I will confirm this with them and their address for reasons of safety. Their address will be on the returned consent form and I will confirm if this is where they currently are. If not, then their location will be ascertained. If I have called a mobile number, I will ask if they are at home, i.e., the address on the returned consent form. If they are not then I will ask for their current location for reasons of safety."

B2) Combat Stress R&D application.



Research Request Form:

- **COMBAT STRESS (EX-SERVICES MENTAL WELFARE SOCIETY)**
- **PROPOSAL FOR EXTERNAL RESEARCH ACCESS**

<p>▪ Title of project: Mediating and moderating effects of maladaptive emotion regulation, injury type and post-concussion symptoms in the relationship between TBI and PTSD in UK military personnel</p>	
<p>Name of researcher(s), including relevant credentials:</p> <p>Mr Mark Rose, BSc (Hons), ConDipPsych, MSc</p> <p>University / Trust / Organisation:</p> <p>University of Exeter Psychology Department</p> <p>Address:</p> <p>Psychology Department, Washington Singer Building, College of Life and Environmental Sciences, University of Exeter, Exeter, EX4 4QG</p> <p>e-mail:</p> <p>mr388@exeter.ac.uk</p>	<p>Name of supervisor(s), including relevant credentials:</p> <p>Professor Huw Williams, Associate Professor of Clinical Neuropsychology and Co-Director of the Centre for Clinical Neuropsychology Research.</p> <p>Dr Anke Karl, Senior Lecturer.</p> <p>University / Trust / Organisation:</p> <p>University of Exeter Psychology Department</p> <p>Address:</p> <p>Psychology Department, Washington Singer Building, College of Life and Environmental Sciences, University of Exeter, Exeter, EX4 4QG</p> <p>Professor Huw Williams:</p> <p>Phone: +44 (0) 1392 264661 email: w.h.williams@ex.ac.uk</p> <p>Dr Anke Karl:</p> <p>Phone: +44 (0) 1392 725271 e-mail: a.karl@exeter.ac.uk</p>

<p>Are you conducting this research project as part of a formal educational or professional course?</p> <p><input checked="" type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>If yes, please provide course title and level of resultant qualification:</p> <p>Doctorate in Clinical Psychology</p>	<p>How is your research being funded?</p> <p><input type="checkbox"/> Self</p> <p><input type="checkbox"/> Grant / Bursary / Sponsorship</p> <p>(please provide brief details)</p> <p><input checked="" type="checkbox"/> Other</p> <p>Research fund held by the University of Exeter for doctorate trainees.</p>
<p>Please provide details of any other individuals or organisations involved in your research project, either financially or in a consulting capacity:</p> <p>NA</p>	
<p>Name (s)</p> <p>University / Trust / Organisation:</p> <p>Address</p> <p>Telephone</p> <p>e-mail</p> <p>Nature of involvement</p>	<p>Name (s)</p> <p>University / Trust / Organisation:</p> <p>Address</p> <p>Telephone</p> <p>e-mail</p> <p>Nature of involvement</p>

- **PURPOSE OF PROJECT AND ITS ACADEMIC RATIONALE:** 113
- **Please ensure that you highlight the intended benefits of this research for this population**

Consequences of the Afghanistan and Iraq conflicts

The recent armed conflicts in Afghanistan and Iraq have had a tremendous impact on the physical and mental health functioning of service members deployed to such war zones. Longer tour lengths (Bruner, 2006) and thus increased exposure to physical and mental health stressors such as being engaged in combat (Hoge, Castro, Messer, McGurk, Cotting & Koffman, 2004), increased survivability rates due to improved head and body armour (Tanielian & Jaycox, 2008) and the high degree of blast-related injuries (Owens, Kragh, Wenke, Macaitis, Wade & Holcomb, 2008) increase the risk of physical trauma and associated conditions such as traumatic head injury (TBI), as well as mood and/or stress-related mental health problems such as post-traumatic stress disorder (PTSD) compared to non-deployed military personnel (e.g., Hoge, Auchterlonie & Milliken, 2006). It is therefore important to understand the unique association between exposure to blast trauma, head injury and PTSD.

Traumatic brain injury (TBI)

TBI is defined as a jolt or blow to the head or a penetrating head injury that disrupts the function of the brain (Martin, Farris, Parker & Epley, 2010). Post-concussional syndrome (PCS) refers to a set of non-specific symptoms that are commonly associated with TBI that may persist for weeks, months or years post-injury. Persistent PCS prevalence is reported to be between 10% and 20% in TBI cases (Iverson & Lange, 2011). Symptoms may include somatic symptoms (e.g. sleep disturbance), cognitive difficulty (e.g., poor memory), and changes to emotions and behaviour (e.g. low mood or irritability).

In UK military personnel, Jones et al. (2014) reported in-theatre rates of 5.9% for at least one potential mTBI exposure during current deployment and 1.6% reported injury plus one or more mTBI symptoms. TBIs are commonly associated with blast-related injuries (e.g. from improvised explosive devices) and accounted for 78% of all injuries in US service members in the Afghanistan and Iraq conflicts between 2001 and 2005 (Jones et al., 2007; Owens et al., 2008). The nature of the injury (blast vs. blunt force) may influence the type of symptoms experienced. Rosenfeld and Ford (2010) report that blast related concussion (compared to non-blast-related concussion) may have more psychological sequelae and a stronger association with PTSD. Mendez, Owens, Jimenez, Peppers and Light (2013) showed in US veterans that blast-related injuries were associated with a greater degree of neuroticism, anger, frustration, toughness and boundary violations compared to blunt-impact injuries.

Post-traumatic stress disorder (PTSD)

PTSD is the inability to recover from psychological trauma such as combat (American Psychiatric Association: APA, 2013). It is observed in approximately 1.3% to 17% of combat

survivors (e.g. Rona et al., 2006) and its likelihood to develop is higher in individuals who have severe physical injuries (Hoge, McGurk, Thomas, Cox, Engel & Castro, 2008). PTSD in military personnel appears to develop slowly over time suggesting a larger extent of delayed onset compared to the general population. For instance, Andrews, Brewin, Philpott and Stewart (2007) reported that over one third of PTSD cases in military samples experience delayed onset compared to 10% to 15% in the general population (NICE, 2005).

TBI and PTSD in military personnel

Co-occurring TBI and PTSD in military personnel are associated with higher rates of psychological and medical problems compared to the general population (Hoge et al., 2004). A dose-response relationship has been shown between TBI and PTSD severity (Hoge et al., 2008; Jones et al., 2014; Rona et al., 2012). However, these studies tell us little about the role that the nature of injury (blast vs. blunt-impact) plays in the onset of PTSD.

Emotional regulation in TBI and PTSD

Military personnel with a history of TBI show an increased risk of problems with the experience, expression and control of anger compared to non-injured counterparts (Bailie et al., 2015). With regards to PTSD, meta-analytic studies have shown PTSD symptom severity is strongly positively associated with anger and aggressive behaviour and that this association is stronger in veterans compared to civilians (Orth & Wieland, 2006; Taft, Watkins, Stafford, Atreest & Monson, 2011). Whilst anger may be a feature of PTSD and PCS, it is probable that it may exacerbate these complaints in its own right. Alcohol misuse may be used as a maladaptive emotional regulation strategy to deal with negative emotions (Harris & Edlund, 2005) and has been reported as one of the most frequent mental health problems in those returning from recent conflicts, particularly in those who have undertaken a combat role (Jones & Fear, 2010). Increased risk for alcohol misuse has been associated with PTSD co-morbidity (Carter, Capone & Short, 2011), PTSD severity (McDevitt–Murphy et al., 2010) and presence of TBI (e.g., Rona et al., 2012; Hoge et al., 2004).

Thus maladaptive emotional regulation strategies (anger and alcohol misuse) may further complicate the association between TBI and PTSD via a mediating effect as well as being involved in the long term persistence of PTSD symptoms. For instance, anger may interfere with the processing of traumatic memories and thus exacerbate PTSD symptoms. The prevention of successful trauma processing by the continued numbing effects of alcohol may also lead to persistence of PTSD symptoms in the long term.

Furthermore, in line with Mendez et al. (2013), exposure to blast relative to blunt force injuries may exacerbate the relationship between TBI and PTSD through its influence on emotional regulation strategies, i.e., blast injuries may act as a moderator of anger and/or alcohol misuse between TBI and PTSD symptoms. Alternately, due the compounding effects

of stressors that occur following the precipitating trauma (e.g., King, King, Foy, Keane & Fairbank, 1999), it is possible that persistent PCS symptoms may drive maladaptive emotional regulation strategies (anger and/or alcohol misuse) that exacerbates PTSD symptoms (Landre, Poppe, Davis, Schmaus & Hobbs, 2006), i.e., persistent PCS symptoms may act as a moderator of anger and/or alcohol misuse between TBI and PTSD symptoms.

This study will have the potential to enhance the understanding of the relationship between the complicating factors of the nature of injury, anger and alcohol use in UK military personnel with co-occurring TBI and PTSD. The hypothesized models are based on current evidence and theory. Such knowledge may shed light on a potential mechanism of development and maintenance of PTSD and provide avenues to inform future research and cognitive treatments. To the author's knowledge, this study has not been done to date.

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RESEARCH QUESTIONS AND HYPOTHESES:

The primary research question will test if maladaptive emotional regulation strategies (i.e. alcohol misuse and anger) mediate the effect that TBI severity has on PTSD symptom severity. It is hypothesized there will be a significant indirect effect via alcohol misuse between the relationship of TBI severity on PTSD severity and a significant indirect effect via increased anger between the relationship of TBI severity on PTSD severity.

The secondary research question will test if the mediating effect of maladaptive emotional regulation strategies between TBI severity on PTSD symptom severity are exacerbated by persistent PCS or having a blast- relative to a blunt-force injury (moderators). It is hypothesized that blast injuries exacerbates the indirect effect of alcohol misuse and anger between the relationship of TBI severity on PTSD severity and that persistent PCS will exacerbate the indirect effects of alcohol misuse and anger between the relationship of TBI severity on PTSD severity.

The tertiary research question will test if maladaptive emotional regulation strategies mediate the effect that TBI severity has on PTSD recovery, i.e., PTSD symptoms at 20 months follow-up. It is hypothesized there will be significant indirect effects via anger and alcohol misuse between the relationship of TBI severity on PTSD severity at 20 months following the initial investigation.

BRIEF DESCRIPTION OF PROCEDURE:

- **Please indicate what practical resources, if any, will be required from Combat Stress. This includes material resources and staff time**

Design

Study A has already been conducted by Murphy and Busuttil at Combat Stress. This application is for a follow-up (Study B) of the Murphy and Busuttil study.

Murphy and Busuttil Study A: Time 1- 184 adults who have served in the British Armed Forces and were undergoing treatment at Combat Stress completed the following questionnaires between January 2014 and July 2014: Impact of Events Scale- Revised (IES-R) to assess PTSD symptoms; Patient Health Questionnaire (PHQ-9) to assess depression symptoms; Generalized Anxiety Questionnaire (GAD-7) to assess anxiety; Alcohol Use Identification Test (AUDIT) to assess alcohol use and Dimensions of Anger Reactions (DAR-5) to assess anger.

Time 2 follow-up: The sample were re-contacted between October 2014 and December 2014 via telephone to administer the Brain Injury Screening Index (BISI) to assess

head injury TBI and PCS questionnaire to assess post-concussion symptoms, of which 123 responded (67% response rate).

Study B: The design of this study is a longitudinal cross-sectional survey. Secondary data analysis of already collected Time 2 data (n=123) will be conducted using direct versus indirect regression analyses.

Time 3 follow-up: In addition, the Time 2 sub-sample will be re-contacted to administer the following questionnaires: Impact of Events Scale- Revised (IES-R) to assess PTSD symptoms 20 months later; one item from the Defense and Veteran's Brain Injury Centre TBI Screening Tool that assesses the cause of head injury- fragment, bullet, vehicular, fall, blast or other; and length of time undergoing PTSD treatment to date, either with Combat Stress or another healthcare organisation. Based on the Time 2 response rate, it is anticipated that approximately 82 individuals will respond to Time 3 follow-up via telephone.

PROPOSED MEASUREMENT TOOLS:

- Please indicate whether your chosen tools are standardized or self-created
- Please include copies of all standardized tools with their original references

All measures are standardized.

Time administered	Domain assessed	Questionnaire (author)	Brief description	Items and scale	Psychometric properties
Time 1	Anger	Dimensions of Anger Reactions (DAR-5: Forbes et al., 2013)	Assesses anger reactions	5 items	Internal reliability $\alpha = .86$
	Alcohol use	Alcohol Use Disorders Identification Test (Babor, Higgins-Biddle, Saunders & Monteiro, 2001)	Screen of alcohol consumption	10 items, 5 point Likert scale	A test-retest reliability $r = .86$
	PTSD symptoms	Impact of Events Scale (IES-R: Weiss & Marmar, 1997)	Assesses PTSD symptoms based on DSM-IV criteria- Intrusion, Avoidance, and Hyperarousal	22 items, 5 point Likert scale	Internal consistency- total score $\alpha = .96$; .94 for Intrusion, ; .97 for Avoidance; .91 for Hyperarousal
	Depression	Patient Health Questionnaire (PHQ-9: Kroenke, Spitzer & Williams, 2001)	Brief measure of depression severity	9 items, 4 point Likert scale	Internal consistency $\alpha = .89$

	Anxiety	Generalised Anxiety Questionnaire (GAD-7: Spitzer, Kroenke, Williams, Löwe, 2006)	Brief measure of anxiety severity	7 items, 4 point Likert scale	Internal consistency $\alpha = .92$. Test-retest reliability $r = 0.83$
Time 2	TBI	Brain Injury Screening Index (BISI; Disabilities Trust Foundation)	Assesses whether suffered a head injury resulting in unconsciousness, dazed or confused state, frequency of head injuries, associated physical and cognitive factors	6 items	
	Post concussion syndrome	Post concussion syndrome screen (used in Hoge et al., 2008; Fear et al., 2009 & Rona et al., 2012)	Assesses 7 symptoms of post concussion syndrome	7 items, 5 point Likert scale	test-retest reliability $r = 0.91$; inter-rater reliability $r = 0.87$
Time 3	Nature of injury	Defense and Veteran's Brain Injury Centre TBI Screening Tool (Schwab, Baker, Ivins, Sluss-Tiller, Lux & Warden, 2006).	Cause of head injury	One item selected, multiple choice	
	PTSD symptoms	Impact of Events Scale (IES-R: Weiss & Marmar, 1997)	Assesses PTSD symptoms based on DSM-IV criteria- Intrusion, Avoidance, and Hyperarousal	22 items, 5 point Likert scale	Internal consistency- total score $\alpha = .96$; .94 for Intrusion, ; .97 for Avoidance; .91 for Hyperarousal

PARTICIPANTS:

- **Recruitment procedure**
- **Number** (please include details of power analyses. If you have not conducted a power analysis, please indicate how you have calculated the number of participants required):
- **Age**
- **Gender**
- **Exclusion / inclusion criteria:**

Participants have already consented for data to be used for research purposes and to be followed up as part of research by Combat Stress. Since this is a follow-up study, all

individuals will have already met the inclusion criteria of having served in the military, of having a TBI and diagnosis of PTSD.

It is proposed that Combat Stress will contact participants via two mail outs between August and October 2015. Consent forms will be returned to Combat Stress. Details of consented participants will then be sent to the lead author who will contact them via telephone to further explain the study and complete the IES-R and Defense and Veteran's Brain Injury Centre TBI Screening Tool. During the telephone conversation, a telephone script will be followed (see appendix C). As detailed in the information sheet, the participant will be told the study is completely voluntary and they can withdraw participation at any time.

It is proposed that Combat Stress provide an anonymised dataset to conduct the secondary data analysis. A second database of consented participants will then be provided for telephone follow-up.

Power analyses

Power analyses are provided for each of the hypotheses. Power calculations were conducted using G Power 3 (Faul, Erdfelder, Lang & Buchner, 2007) unless otherwise stated.

Hypothesis 1: Fritz and MacKinnon (2007; Table 3, page 237) informed the power calculation for analysis of single mediation models using bias corrected bootstrapping. Based on medium effect sizes for path *a* and *b* (the indirect or mediator path), power = 0.80 and alpha = 0.05, the minimum required sample size is 71. Medium effect sizes was chosen as Rona et al. (2012), a UK based study (in line with this study) showed a range of effect sizes- a large effect size for the association between mTBI and PTSD, and medium for mTBI and alcohol misuse and PCS. The existing data set of 123 participant is therefore sufficient to detect a medium effect size.

Hypothesis 2: Mendez et al. (2013) found a large effect size for the difference in anger and irritability between blast versus blunt force injuries in military veterans. In the absence of specific research that has investigated the indirect role of blast injuries, the effect size of the direct effect found by Mendez et al. (2013) will be used as a proxy for the indirect effect of blast vs. blunt force injuries. Preacher, Rucker and Hayes (2007; Table 4, page 206) informed the power calculation for the analysis of single moderated mediation using bias corrected bootstrapping. Based on medium effect sizes for paths *a*, *b*, and *a* by moderator interaction, a sample size $n = 50$ gives power = 0.706 whilst a sample size $n = 100$ gives power = 0.962. Based on large effect sizes, $n = 50$ gives power = 0.970 whilst $n = 100$ gives power = 1.000. The anticipated sample size of 82 participants therefore allows detection of medium to large effects.

Hypothesis 3: Hoge et al. (2007) found a large effect size for alcohol misuse in those who met chronic PTSD diagnostic criteria (one year post traumatic event) compared to non-chronic PTSD cases in military veterans. This will be used as a proxy for PTSD recovery. Fritz and MacKinnon (2007; Table 3, page 237) informed the power calculation for analysis of single mediation models using bias corrected bootstrapping. Based on medium effect sizes for path

a and *b* (the indirect or mediator path), power = 0.80 and alpha = 0.05, the minimum required sample size is 71. Based on large effect sizes for path *a* and *b* (the indirect or mediator path), power = 0.80 and alpha = 0.05, the minimum required sample size is 34. The anticipated sample size of 82 participants therefore allows detecting medium to large effects.

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PARTICIPANT INFORMATION ARRANGEMENTS, INFORMED CONSENT AND DEBRIEFING:

- **Please provide copies of information sheets, consent forms and written debriefs where applicable**

The lead author has prepared documents (cover letter, see appendix A; information sheet and returnable (to Combat Stress) consent form (see appendix B) which will mail out to the 123 participants.

ETHICAL CONSIDERATIONS:

- **Please answer questions a – e as fully as possible**

a) Is there any realistic risk of any participants experiencing either physical or psychological distress or discomfort as a result of participating in this research?

It is possible that some of the questionnaires could lead to discomfort or distress.

b) What precautions will be taken to minimize any such risks, and to deal with their potential consequences?

Regarding risk management, the following procedures have been agreed with Combat Stress. At the beginning of the telephone interview, participants will be informed that their responses will be confidential and anonymous. However, if risky behaviours are disclosed,

such as risk of harm to self or others, then the following procedure will be followed. If mild to moderate risk is declared then the lead author will inform the participant that such a risk has been disclosed and shall inform Combat Stress. The lead author will also recommend that the participant either speak to their Combat Stress Community Team Mental Health worker or call the Combat Stress 24 hour helpline which is manned 24 hours a day. Participants who call this would then be supported by Combat Stress. If appropriate, other sources of support, such as their GP or citizens advice bureau would also be recommended. If an immediate high risk is declared then the lead author will take action, informing the participant that a high risk behaviour has been disclosed and that 999 will be contacted to inform emergency services. Combat Stress will also be contacted to inform them of this action. Two named individuals have been identified at Combat Stress who the lead author would contact to inform them of risk issues- Emily Palmer (research assistant) and Dr. Dominic Murphy (clinical psychologist). This procedure is operationalised at the end of the telephone script (see appendix C).

Low, moderate and high risk will be operationalised based on British Medical Journal Best Practice (2015) guidelines (<http://bestpractice.bmj.com/best-practice/monograph/1016/diagnosis/step-by-step.html>). The following components will be assessed- 1) intent, 2) plan, 3) access to means, 4) lethality means and 5) history of risk. Levels of risk will be established as follows:

None- No suicidal ideation

Low- Some ideation, no plan

Moderate- Ideation, vague plan, low on lethality, client says they would not do it

High- Ideation, a plan that is both specific and lethal, and client saying they are going to act out on their plan.

The focus of the telephone interview will be on current symptoms only based on IES-R (PTSD symptoms over the last seven days), the nature of head injury/ies and whether they are undergoing or have already received treatment for PTSD. If participants wish to discuss matters beyond these then the leader author shall direct them back to Combat Stress or other sources of support (e.g their GP) as appropriate. The lead author will also inform Combat Stress of these discussions as well.

Furthermore, the information sheet details the following telephone help lines and websites for support:

- Combat Stress. Helpline: 0800 1381 619 (manned 24 hours)
- Post traumatic stress disorder. www.ptsd.org.uk. For ex-servicemen and women, and anyone who has PTSD.

- Anxiety UK. Helpline: 08444 775 774 (Monday to Friday 9.30am to 5.30pm), www.anxietyuk.org.uk. Provides fact sheets for anxiety disorders (including PTSD).
- ASSIST trauma care. Helpline: 01788 560 800, www.assisttraumacare.org.uk. Support, understanding and therapy for people experiencing PTSD, and families and carers.

Additional sources of support to offer during telephone interview (if deemed appropriate):

- Citizens advice bureau- national number 03454 04 05 06.
- NHS Choices website www.nhs.uk or NHS 111 non-emergency number.

The lead author's contact details (university email address and work mobile number) will be provided in the information sheet if participants have any concerns they would like to discuss. Any issues arising from this project would be discussed with my research supervisors and field collaborator Dr Dominic Murphy.

c) What provision will be made in the form of insurance and / or indemnity to meet potential legal liability for physical or psychological harm to participants?

As a trainee clinical psychologist for Taunton and Somerset NHS Foundation Trust, the lead author is covered for insurance and indemnity.

d) How will you ensure the security and confidentiality of participants' data?

Combat Stress have agreed to anonymise any data that will be sent to the lead author. Furthermore, only contact details of participants that have consented will be provided to the lead author. All information will be kept strictly confidential. A log of participant names and ID codes will be held by the lead author. All data will be held on a password protected computer with access restricted to the first author, supervisors and the research team.

e) Are you aware of any other ethical considerations pertaining to this research? If so, please briefly state the considerations, and how you intend to deal with them.

It is deemed there are no other ethical considerations that have not already been declared.

ETHICAL APPROVAL:

NHS LREC Chair:

Address:

Telephone:

e-mail:

Please tick one of the following options:

☐ **My research has been approved by this Ethics Committee and I enclose written confirmation of their decision**

☐ **I am awaiting a decision from this Ethics Committee, which is expected by / /**

University Ethics Committee Chair:

Dr Tim Kurz, Senior Lecturer

Address:

Office: WSL 111

Psychology

College of Life & Environmental Sciences

Washington Singer Laboratories

University of Exeter

Perry Road

Exeter EX4 4QG

Telephone: 01392 72 4657

e-mail: t.r.kurz@exeter.ac.uk

Please tick one of the following options:

X My research has been approved by this Ethics Committee and I enclose written confirmation of their decision

University of Exeter Ethics Committee approval forwarded with this application.

☐ **I am awaiting a decision from this Ethics Committee, which is expected by / /**

▪ ESTIMATED START DATE AND DURATION OF PROJECT:

It is anticipated to begin data collection in August 2015. The project will need to be submitted in May 2016.

B3) Combat Stress R&D approval.

RE: PTSD-mTBI project - Rose, Mark

Page 1 of 2

RE: PTSD-mTBI project

Dr Dominic Murphy <Dominic.Murphy@combatstress.org.uk>

Fri 07/08/2015 08:56

To: Rose, Mark <mr388@exeter.ac.uk>;

Cc: Williams, Huw <W.H.Williams@exeter.ac.uk>; Karl, Anke <A.Karl@exeter.ac.uk>; Walter Busuttill <Walter.Busuttill@combatstress.org.uk>;

Hello Mark,

Well done and now we have your ethics we can start thinking about data collection!

BW
Dominic

From: Rose, Mark [mr388@exeter.ac.uk]
Sent: 06 August 2015 22:30
To: Dr Dominic Murphy
Cc: Williams, Huw; Karl, Anke; Walter Busuttill
Subject: PTSD-mTBI project

Hi Dominic,

I have now received ethical approval from the University of Exeter for the proposed study, please see forwarded approval confirmation below.

I have attached the Combat Stress research application form alongside supporting documents-

Appendix A- cover letter, appendix B- information sheet and consent form, appendix C- telephone script to be used during follow-up.

The information and consent sheet need to be updated with my work mobile number which I'm in the process of sorting out.

I look forward to hearing from you with regards to the next steps in this collaboration.

Regards

Mark

Appendix C: Extended data analysis

1) Power analyses.

To the authors knowledge, no research has directly investigated the indirect effects in the variables of interest in this study, thus where available, prior research conducted on similar populations were used as a proxy for the effect sizes used in the power calculations. Power calculations were conducted using G Power 3 (Faul, Erdfelder, Lang & Buchner, 2007) unless otherwise stated.

Determination of required sample sizes for the single mediation models was based on studies by Rona et al. (2012) who reported a large effect size for the association between mTBI and PTSD in UK military veterans and Hoge et al. (2007) who reported a large effect size for alcohol use in those who met chronic PTSD diagnostic criteria (one year post traumatic event) compared to non-chronic PTSD cases in military veterans. Fritz and MacKinnon (2007; Table 3, page 237) informed the power calculation for single mediation model analyses using bias-corrected bootstrapping. Based on medium effect sizes for path *a* and *b* (mediator path), power = .80 and alpha = .05, the minimum required sample size was 71, whilst large effect sizes for path *a* and *b*, power = .80 and alpha = .05 required a minimum sample size is 34.

2) Table C2.1: Based on included sample of 116 veterans, comparison of demographic and clinical characteristics of non-responders vs. responders.

Variable	Non-responder (n=82)	Responder (n=34)	Test statistic ^b	<i>p</i> value	Effect size ^c
	N	N			
	(%)/Mean	(%)/Mean			
	(sd)/Median	(sd)/Median			
	(25-75 percentile) ^b	(25-75 percentile) ^b			
Demographics					
Age	46.26 (11.27)	48.47 (15.59)	-0.857	0.393	0.162 ^x
Gender ^a	80/2 (97.6/2.4)	34/0 (100/0)	-	-	-

	(male/female ratio)					
Service	-	-	2.157	0.540	0.136 ^y	
Army	63 (76.8)	27 (79.4)	-	-	-	
Royal Navy	13 (15.9)	3 (8.8)	-	-	-	
Royal Air Force	3 (3.7)	3 (8.8)	-	-	-	
Royal Marines	3 (3.7)	1 (2.9)	-	-	-	
Clinical characteristics						
TBI status	-	-	4.533	0.033	0.218 ^y	
Present	49 (59.8)	28 (82.4)	-	-	-	
Not present	33 (40.2)	6 (17.6)	-	-	-	
TBI severity ^a						
None	33 (40.2)	6 (17.6)	-	-	-	
Minor concussion	16 (19.5)	9 (26.5)	-	-	-	
mTBI	22 (26.8)	16 (47.1)	-	-	-	
Complicated mTBI	4 (4.9)	1 (2.9)	-	-	-	
Moderate TBI	7 (8.5)	2 (5.9)	-	-	-	
Mental health outcomes						
PCS total	5 (3-6)	5 (3-6)	1,652	0.109	0.153 ^z	
DAR-5	14 (12-19)	16 (11-20.25)	1,382	0.807	0.023 ^z	
AUDIT	8 (3-15.5)	6 (2-12.5)	1,094	0.250	0.110 ^z	
PCS total	5 (3-6)	5 (3-6)	1,652	0.109	0.153 ^z	

Notes. ^a Chi-square test of independence was not conducted for gender and TBI severity due to violation of minimum expected cell frequency assumption. ^b Chi-square test of independence for categorical data, frequency with percentage displayed; independent samples t-test test statistic for comparisons of normally distributed data, mean values displayed with standard deviations; Mann-Whitney U test statistic for data not normally distributed, median values displayed with upper and lower quartiles. ^c Effect sizes, those marked ^x are Cohen's *d*, ^y are phi coefficients, and ^z are *r*.

3) Table C3.1. Frequencies of veterans for each TBI severity rating at included Time 1 and Time 2.

	Time 1 (n=116)	Time 2 (n=29)
	N (%) / Mean (sd)	N (%) / Mean (sd)
TBI severity		

None	39 (33.6)	5 (17.2)
Minor concussion	25 (21.6)	8 (27.6)
mTBI	38 (32.8)	13 (44.8)
Complicated mTBI	5 (4.3)	1 (3.4)
Moderate TBI	9 (7.8)	2 (6.9)

Notes: sd= standard deviation

4.1) Table C4.1. Model 1 coefficients for alcohol use mediating the effect of TBI severity on PTSD severity.

		Consequent							
		M AUDIT				Y IES-R total			
Antecedent			b	SE	p		b	SE	p
X	TBI severity	<i>a</i>	-0.106	0.730	.885	<i>c'</i>	4.023	1.851	.032
M	AUDIT		-	-	-	<i>b</i>	0.470	0.246	.059
Constant		<i>i1</i>	10.024	1.264	<.001	<i>i2</i>	37.212	4.046	<.001
		<i>R</i> ² = 0.000, <i>F</i> (1, 106) = 0.021, <i>p</i> = .885					<i>R</i> ² = 0.073, <i>F</i> (2, 105) = 4.121, <i>p</i> = .019		

Notes: b= unstandardised regression coefficient; SE= standard error; X= predictor TBI severity; M= mediator alcohol use; Y= outcome PTSD severity.

4.2) Table C4.2. Model 2 coefficients for anger mediating the effect of TBI severity on PTSD severity.

		Consequent							
		M DAR-5				Y IES-R total			
Antecedent			b	SE	p		b	SE	p
X	TBI severity	<i>a</i>	0.815	0.433	.063	<i>c'</i>	3.168	1.767	.076
M	DAR-5		-	-	-	<i>b</i>	1.423	0.390	<.001
Constant		<i>i1</i>	14.348	0.751	<.001	<i>i2</i>	20.675	4.725	<.001
		<i>R</i> ² = 0.032, <i>F</i> (1, 106) = 3.536, <i>p</i> = .063				<i>R</i> ² = 0.157, <i>F</i> (2, 105) = 9.766, <i>p</i> = <.001			

Notes: b= unstandardised regression coefficient; SE= standard error; X= predictor TBI severity; M= mediator anger; Y= outcome PTSD severity.

Appendix D: Dissemination statement

The results of this study will be disseminated to interested parties through feedback, journal publication and presentation.

Dissemination to participants and Combat Stress.

As stated on the participant information sheet, participants that expressed wanting be informed of the results of the study will be sent a summary of the findings. Participants will be provided with details of who to contact, should they require further information. Additionally, Dr. Dominic Murphy at Combat Stress will be provided with a summary of the findings. The research ethics committee at the University Exeter will be sent a summary of the findings of the study and will be informed that the study is now complete.

Journal Publication.

It is expected that the study will be submitted for publication with the Journal of Psychological Medicine.

Presentation.

On the 13th June 2016, my research findings will be presented to an academic audience, for peer review, as part of the Doctorate in Clinical Psychology at the University of Exeter.